SCHOOL OF BIOSCIENCE AND BIOMEDICAL ENGINEERING

# GALGOTIAS UNIVERSITY

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# COURSE BOOK

## School of Bioscience and Biomedical Engineering-2020

## Volume- I

Curriculum and syllabus for School of Bioscience and Biomedical Engineering

GALGOTIAS UNIVERSITY
(Under the Uttar Pradesh Private Universities Act No. 12 of 2019)

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GALGOTIAS UNIVERSITY

(Established under Galgotias University Uttar Pradesh Act No. 14 of 2011)

# Program: B.Sc Healthcare and Clinical Research

**Scheme: 2020-2021**

**Vision: -** To be known globally for education, innovation and interdisciplinary research in Biosciences, Healthcare and Biomedical Engineering.

**Mission:**

**M1**. To establish the center of excellence in Healthcare & Clinical research.

**M2**. To establish state-of-the-art facilities of Clinical research for world class education and research.

**M3**. To conduct the multidisciplinary research in collaboration with national and international organization for developing the innovative solutions of unsolved health problems.

**M4**. To develop clinical research leaders having regulatory and ethical mindset with capability of creating value in clinical research industry.

**Program Educational Objectives:**

**PEO** 1. Graduates shall conduct the clinical trials, research in healthcare and interdisciplinary field efficiently and ethically.

**PEO** 2. Graduates of clinical research shall excel in higher studies and interdisciplinary research exhibiting global competitiveness.

**PEO** 3. Graduates have a high sense of medical responsibilities and ethical thinking and solve new/unsolved/unmet medical need.

**Program Specific Objectives:**

**PSO**1. Evaluate critical domestic and global regulatory and health care issues that challenge and influence biopharmaceutical product development

**PSO**2. Demonstrate competencies in performing the clinical research; evaluating, analysing and presenting the clinical research results.

**PSO**3. Effectively communicate and collaborate with health care providers and regulatory agencies to develop culturally diverse domestic and global strategies for biopharmaceutical product approvals

**PSO**4. Demonstrate regulations, social and ethical values required to make a global clinical research professional responsible in their career

**Program Outcomes:**

**PO**1- Clinical Research Knowledge: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of clinical Research, including regulatory guidelines, Drug Development and Drug safety, Ethical aspects in Clinical Research, Pharmacovigilance and Sponsor, Hospital and Investigator responsibilities in clinical trial, Bioavailability and Bioequivalence studies.

**PO**2- Planning Abilities: Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

**PO**3- Problem analysis: Utilize the principles of Analytical thinking, clearly and critically, while solving problems and making decisions during clinical trials. Find, analyze, evaluate and apply information systematically and making decisions related to clinical trial.

**PO**4- Modern tool usage: Learn and apply modern and appropriate tools related to clinical research. As example, Drug Designing, Statistical Analytical System (SAS), Clinical Oracle and ARGUS and Pharmacokinetic software's.

**PO**5- Leadership skills: Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles during the conduction of clinical trial to facilitate improvement in health and wellbeing.

**PO**6- Professional Identity: Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, Clinical Researcher, managers, employers, employees)

**PO**7- Clinical Research Ethics: Honor human values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions during the conduction of clinical trial and selection of the volunteers.

**PO**8- Communication: Communicate effectively with the Clinical research community (healthcare provider, doctor and patient and write effective reports, make effective presentations and documentation, and give and receive clear instructions.

**PO**9- The clinical research and society: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the Clinical Research practice.

**PO**10- Environment and sustainability: Understand the impact of the Clinical research solution in societal and environmental contexts, demonstrate the knowledge of, and need for sustainable development.

**PO**11- Life-long learning: Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self access and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

# Curriculum

| Semester 1 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sl. No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BSCRT 1001 | Fundamentals of Clinical Research | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BSCRT 1002 | Introduction to Healthcare | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BSCRT 1003 | Human Physiology-I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | | Disruptive technologies | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 5 | | Professional communication | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | | Environmental Studies | 0 | 0 | 1 | 0.5 | 50 | - | 50 |
| 7 | | Campus to corporate | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 8 | | Ethics and Professional Competency | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 9 | | Creative / Liberal Arts | 0 | 0 | 1 | 0.5 | 50 | - | 50 |
| 10 | | Waste management | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 11 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **20** | **0** | **2** | **21** | **280** | **270** | **550** |
| **Semester II** | | | | | | | | | |
| Sl No | Course Codee | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BSCRT 2001 | Basic Biochemistry | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BSCRT 2002 | Research Methodology and Biostatistics | 4 | 0 | 0 | 4 | 20 | 30 | 50 |
| 3 | BSCRT 2003 | Microbiology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BSCRT 2004 | Human Physiology-II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | BSCRT 2005 | Regulatory Affairs - I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | BSCRP 1051 | Clinical Research Lab -I | 0 | 0 | 4 | 2 | 50 | - | 50 |
| 7 | | Professional communication | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 8 | | Foreign Language | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 9 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **22** | **0** | **4** | **24** | **210** | **240** | **450** |
| **Semester III** | | | | | | | | | |
| Sl No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BSCRT 3001 | Regulatory Affairs-II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BSCRT 3002 | Drug Discovery and Development | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BSCRT 3003 | Aspects of Clinical Trials Operations | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BSCRT 3004 | Ethical Guidelines in Clinical Trial | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | BSCRP 3051 | Computer Lab | 0 | 0 | **4** | 2 | 50 | - | 50 |
| 6 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 7 | | Disaster Management | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 8 | | AI and its application | 0 | 0 | **4** | 2 | 50 | - | 50 |
| 9 | | Creativity, Innovation and entrepreneurship and IPR | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **16** | **0** | **8** | **20** | **210** | **240** | **450** |
| **Semester IV** | | | | | | | | | |
| Sl No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1 | BSCRT 4001 | Pharmacology-I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BSCRT 4002 | Designing Clinical trials | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BSCRT 4003 | Basics of Pharmacovigilance | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BSCRT 4004 | Medical Microbiology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | BSCRT 4005 | Basic Biotechnology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | BSCRP 4051 | Clinical Research Lab - II | 0 | 0 | 4 | 2 | 50 | - | 50 |
| 7 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **16** | **0** | **4** | **18** | **170** | **180** | **350** |

**Semester V**

| Sl No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BSCRT 5001 | Clinical Data Management | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BSCRT 5002 | Pharmacology-II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BSCRT 5003 | Electrophysiology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BSCRT 5004 | Hospital and Healthcare Administration | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | BSCRT 5005 | Clinical trial amended rule | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | BSCRT 5006 | Molecular Diagnostics & Therapeutics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 7 | Elective | Elective | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 8 | BSCRP 5051 | Clinical Research Lab-V | 0 | 0 | **4** | 2 | 50 | -- | 50 |
| | | **Total** | **21** | **0** | **4** | **23** | **190** | **210** | **400** |

**Semester VI**

| Sl No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | C | IA | MTE | ETE |
| **1** | BSCRP6051 | Clinical project and dissertation | 0 | 0 | 28 | 14 | 60 | 00 | 240 |
| | | **Total** | **0** | **0** | **28** | **14** | **60** | **00** | **240** |

## List of Electives

**Elective**

| Sl No | Course Code | Name of the Electives | | | | | Assessment Pattern | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BSCRT5007 | Medical writing | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BSCRT5008 | Clinical Trial Management | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BSCRT5009 | Bioethics and Biosafety | 3 | 0 | 0 | 3 | 20 | 30 | 50 |

# Detailed Syllabus

| Name of The Course | Fundamentals of Clinical Research | | | |
|---|---|---|---|---|
| Course Code | BSCRT1001 | | | |
| Prerequisite | | | | |
| Co-requisite | | | | |
| Anti-requisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**

1. Students will be exposed to Clinical Research and their requirements, Pharmaceutical Industry, Bioavailability and Bioequivalence Studies.

**Course Outcomes**

| | |
|---|---|
| **CO1** | Historical Aspects of clinical research, clinical research terminologies |
| **CO2** | Phases of Clinical Trial and Types of Clinical Trial including Virtual Clinical Trials |
| **CO3** | Pharmaceutical Industry and concepts of Intellectual Property Rights |
| **CO4** | Modules of International Conference on Hormonization (Quality, Safety, Efficacy and Miscellaneous) and E6 Overview |
| **CO5** | Drug Regulation and Evidence based medicine |
| **CO6** | Analysis of Evidence-based medicine |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Exam (MTE) | End Term Exam (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit I: Basic Introduction to Clinical Research**<br><br>**7 Hours** |
|---|
| Overview, Opportunities & Career options in Clinical Research, Glossary of GCP. Historical Aspects of clinical research, Brief description of different phases, Stakeholders in clinical research, Need/Area for clinical research. |
| **Unit-2 Phases and Types of Clinical Trials 7 Hours** |
| Introduction to Clinical Trials – Phases of Clinical Trials, Types of Clinical Trials, Randomized/Non randomized Clinical Trial, Virtual-clinical trials, Drug discovery and development. |
| **Unit-3 Pharmaceutical Industry & globalization 7 Hours** |
| Overview of global and local players, Intellectual Property Rights: Introduction, Scope, Objectives and concepts of IPR, Tangible & Intangible property, scope & nature of patents, copyrights, trademark, Indian Patent Act 1970, practical aspects of patent filing. |
| **Unit-4: ICH Introduction 7 Hours** |
| ICH Introduction, Origin, Organization, Structure, Modules of ICH (Quality, Safety, Efficacy and Miscellaneous), E6 Overview |
| **Unit-5: Introduction to Indian GCP and ICMR 5 Hours** |
| Indian- good clinical practice, Overview of ICMR |
| **Unit-6: Evidence-based medicine** |
| Need for evidence based approach in making decisions in family medicine; difference between evidence based medicine and evidence based health care; classification of evidence – information levels; 5 steps process for use of evidence oriented approach in family medicine |

**Suggested Reading**


1. Indian GCP Guideline.
2. NDCT 2019
3. Design and Analysis of Clinical Trials: Concepts and Methodologies, 3rd Edition. SheinChung Chow, Jen-Pei Liu. Publisher: Wiley.
4. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Publisher: Wiley-Blackwell
5. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., Dupin-Spriet T., Simon P. Publisher: Karger

| Name of The Course | Introduction to Healthcare | | | |
|---|---|---|---|---|
| Course Code | BSCRT1002 | | | |
| Prerequisite | | | | |
| Co-requisite | | | | |
| Anti-requisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**

Introduction to Healthcare exposes a student to learn Healthcare system, Hospital Role, Infection control, and foundation of health.

**Course Outcomes**

| | |
|---|---|
| **CO1** | Healthcare systems and Ethical Roles and Responsibilities of a Health Care Worker |
| **CO2** | Holistic Health and Controlling Infection, Mental Health, Nutrition, Controlling Infection |
| **CO3** | Foundation of health and healthcare system, Community Medicine and Hospitals |
| **CO4** | Introduction to Primary healthcare, state & district level including Municipal Corporations & Councils |
| **CO5** | Role of Hospital in healthcare system, National Rural and Urban Health Mission |
| **CO6** | Inventory Control & Purchase Management |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Exam (MTE) | End Term Exam (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit I: Healthcare Systems**<br>**7 hours** |
|---|
| Careers in Health Care, Personal Qualities of a Health Care Worker/Health Care Providers, Measurement, Medical Terminology, Legal Obligations, Cultural Considerations, Medical Liability and Patient's Rights, Ethical Roles and Responsibilities of a Health Care Worker |
| **Unit II:Health Control**<br>**7 Hours** |
| Holistic Health, Mental Health, Nutrition, Controlling Infection, Measuring Vital Signs and other Clinical Skills, Injury and Prevention, First Aid/ CPR |
| **Unit III: Foundations of Health and Healthcare System 7 hours** |
| Concept of health & disease: Concept of Prevention, Preventive Medicine, History of Hospitals. Characteristics Hospitals as industry, Community Medicine & Hospitals |
| **Unit IV: Introduction to Primary Health Care**<br>**7 hours** |
| Definition, Principles, Functions, Evolution of Health Care System. Organisation of Health Services at central, state & district level including Municipal Corporations & Councils, Panchayat Raj institutions. Inter-sectoral linkages |
| **Unit V:Role of hospitals in health care system**<br>**7 hours** |
| National health policy, National Rural and Urban Health Mission. National Health Programmes. International Health Agencies, Concepts of family welfare, National Family Welfare programme. MCH and RCH programmes |
| **Unit VI: Inventory Control & Purchase Management 5 Hours** |
| Inventory Control & Purchase Management-meaning & significance. Purchasing & procurementPrinciples of sourcing, purchase methods & procedures, legal aspects of purchasing. Reference to Contract Act, Sale of Goods Act, Drug Control Act in respect to purchase activities. Import substitution |

**Suggested Reading**


1. 1. Health Care Reforms in India – Rajendra Pratap Gupta
2. Introduction to Health Care – SHARON B. BUCHBINDER & NANCY H. SHANKS
3. Innovation in Health Care Management- VK Singh n Paul Lillrank
4. India's Healthcare Industry – Lawton Robert Burns

| **Name of The Course** | **Human Physiology-I** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT 1003** | | | |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50 % marks in aggregate | | | |
| Corequisite | Basic knowledge of physiology. | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:** Students are able to understand the basic concept of Physiology and they can apply the knowledge of physiology in understanding the various .diseases and keeping the body in healthy state.

**Course Outcomes**

| | |
|---|---|
| CO1 | Understand the Digestive system. |
| CO2 | Interpret the composition of blood and its function circulatory system of human |
| CO3 | Interpret the circulatory system in human |
| CO4 | Evaluate the respiratory system |
| CO5 | Understand the excretory system. |
| CO6 | Analyze the Male Reproductive system |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| Unit-1 Digestive system | **7 Hours** |
|---|---|
| Digestive system – Homeostasis, structure of stomach and intestine, Digestive gland and Hormones, Digestion of food in different parts of alimentary canal, absorption and assimilation. | |
| Unit-2 Blood and circulation | **7 Hours** |
| Blood and circulation - Blood corpuscles, hemopoieses and formed elements, plasma function, blood volume, WBC and platelets function. Anemia, thalassemia, Leukemia, Polycythemia, Hemostasis and blood coagulation mechanism, blood groups and blood banking. hematocrits value | |
| Unit-3 Cardiovascular System | **7 Hours** |
| Cardiovascular System: Comparative anatomy of heart structure, myogenic heart, specialized tissue, ECG – its principle and significance, cardiac cycle, heart as a pump, blood pressure, neural and chemical regulation. | |
| Unit-4 Respiratory system | **7 Hours** |
| Respiratory system – structure of lungs and surfactant function, Mechanism of breathing, anatomical considerations, alveolar ventilation, vital capacity of lungs, transport of gases, exchange of gases, waste elimination, neural and chemical regulation of respiration. | |
| Unit-5 Excretory system | **7 Hours** |
| Excretory system - Comparative physiology of excretion, kidney, urine formation, urine concentration, waste elimination, micturition, regulation of water balance, blood volume, blood pressure, electrolyte balance, acid-base balance. | |
| Unit-6: Male Reproductive system **5 Hours** | |
| Testis, Duct system, Functions. Semen-secretion, composition, Oligozoospermia. | |

**Suggested Readings**


1. Guyton A.C, Hall J.E, Textbook of Medical Physiology, 11th Ed., Saunders Company, 2005.
2. Widmaier E. P, Raff H, Strang K. T. Vander's, Human Physiology : The mechanism of Body Function, 9th Ed. Mc. Graw Hill, 2003.
3. Ganong W. E, Review of Medical Physiology, 21st Ed., Mc. Graw Hill, 2003.


# Semester-II

| **Name of The Course** | **Basic Biochemistry** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT2001** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

This course Biochemistry-1 deals with the acid base balance, biochemical nature of carbohydrates, proteins, minerals, vitamins, lipids etc. A detailed study of these, emphasizing on their chemical composition and their role in metabolism is the required aim of this course.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Acid Base balance, Structure, function and interrelationship of bio molecule |
| CO2 | Different types of carbohydrates and their structure and function |
| CO3 | Amino acids & Proteins and Chemical bonds involved in protein Structure |
| CO4 | Types of Lipids, properties & functions of fatty acids, Saturated and Unsaturated Fatty acids and biological significance of fats |
| CO5 | Base Composition of Nucleic acids, deficiency disorders of Vitamins and Minerals |
| CO6 | Analyze the mechanism of enzyme's action |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content:**

| |
|---|
| **Unit-1: Introduction of Acid, Base and Salt 7 hours** |
| Introduction, Definition, Structure of Water molecule, basic concept of Acids, bases, salts & acid base balance, buffer System, Structure of cell & introduction to Atoms and chemical bonds. |
| **Unit-2: Carbohydrates 7 hours** |
| Introduction, Sources, Classification, fischer projections, The artificial or synthetic sweeteners, Haworth perspective formula, Isomerism, important derivatives of monosaccharides, Structure and functions of sugars- disaccharides & polysaccharides. |
| **Unit-3: Amino Acids and Proteins 7 hours** |
| Introduction, Classification, Properties of Proteins, Peptide bond, Amino acids, Peptides, Chemical bonds involved in protein Structure, Derived protein, Ramachandran plot, Myoglobin. |
| **Unit-4 : Lipids 7 hours** |
| Introduction, sources, nomenclature, classification, structure, properties & functions of fatty acids, Saturated and Unsaturated Fatty Acids, Derived Lipids, steroids, biological significance of fats ,cholesterol and phospholipids |
| **Unit-5: Nucleic Acid, Vitamins and Minerals 7 hours** |
| Introduction, Definition and Base Composition of Nucleic acids, helical Structure, Nomenclature and Classification of Enzymes, deficiency disorders of Vitamins and Minerals. |
| **Unit-6: Enzymes 5 hours** |
| Structure of enzyme: Apoenzyme and cofactors, prosthetic group-TPP, coenzyme NAD,metal cofactors; Classification of enzymes; Mechanism of action of enzymes: active site, transition state complex and activation energy |

**Suggested Readings:**

1. S. Ramakrishnan, K G Prasannan and R Rajan: Text book of Medical Biochemistry, Orient Longman, Madras, 1990

2 Das, Debajyothi, Biochemistry, Academic, Publishers, Calcutta.

3 A Text book of Medical Biochemistry by. Chatterjee,

4 A Text book of Biochemistry by Satyanarayan,U.

5 Fundamentals of Biochemistry- J L Jain, Sanjay Jain, Nitin Jain

| **Name of The Course** | **Research Methodology & Biostatistics** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT 2002** | | | |
| **Prerequisite** | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 4 | 0 | 0 | 4 |

**Course Objectives**:

Students will get exposure about Research Methodology

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Research |
| CO2 | Understand about the Research Design |
| CO3 | Understand about the Research Report and ethics |
| CO4 | Understand about the Sampling methods |
| CO5 | Understand about the Measures of central tendency |
| CO6 | Understand about Hypothesis testing |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Introduction to Research** | 8 hours |
|---|---|
| Research definition, types, advantage and significance. Introduction to research methods, identifying research problem, definition, objectives, role, scope in biotech research, process of research, limitations & types | |
| **Unit-2: Research Design** | 7 hours |
| Concept of Interdisciplinary Research, Procedures in research. Types of Research Design: Experimental/Interventional research, Quasi-experimental studies, Observational research. Sources of Experimental Errors. Survey research: Types of surveys- CATI, CAPI, Mail, Email, Face-to-face, Questionnaire | |
| **Unit-3: Research Report and ethics** | 5 hours |
| Type of research report- Research, review, case report, manuscript, monograph, book chapters. Structure of Research Reports. Quoting of reference and bibliography using reference management tools. Ethical issues in research, plagiarism. | |
| **Unit-4: Sampling methods** | 5 hours |
| Sampling methods, Advantages and Limitation, Sampling process, Types of Sampling, Probability and Non Probability sampling techniques, sampling errors, Data collection Primary and secondary data, Collection and validation. | |
| **Unit-5: Measures of central tendency** | 8 hours |
| Measures of central tendency- Mean, Median, Mode; Measures of dispersion- Range, Mean deviation and Coefficient of variation, Standard deviation, Standard error; Correlation and regression; Statistical inference- Hypothesis testing, Significance level, Confidence interval, t-test, z-test. Test of significance for large and small samples; Parametric tests; Non parametric tests; Experimental design, Use of biostatistic softwares. | |
| **Unit-6: Hypothesis testing** | 7 hours |
| Null hypothesis and test of significance (t-test, paired t-test, Analysis of variance, Analysis of covariance, Coefficient of Variation, chi-square test, Fischer exact, Mann-Whitney, Wilcoxin, McNeman test, Kruskal Wallis. | |

**Suggested Readings**:


1. Graziano AM, Raulin ML. Research methods: A process of inquiry. HarperCollins College Publishers; 1993.
2. C.R. Kothari : Research Methodology, New Age International Publishers
3. Bouma GD, Ling R, Wilkinson L. The research process. Oxford: Oxford University Press; 1993 Mar 30.
4. Dawson B, Trapp RG. Basic and clinical biostatistics. Singapore. 2004;2001:141-2.


| **Name of The Course** | **MICROBIOLOGY** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT2003** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

Pharmaceutical microbiology deals with common pathogenic microorganisms, their cultivation methods, sterilization methods, assays. The micro org. causes diseases & contamination the subject deal with all these**.**

**Course Outcomes**

**On completion of this course the students will be able to understand**

| | |
|---|---|
| CO1 | different types of microorganisms and their structure |
| CO2 | Identification of Microbes and types of staining techniques |
| CO3 | staining, cultivation of microbes and methods of sterilization & sterility testing |

| | |
|---|---|
| CO4 | Microbial Physiology and Genetics including Microbiology of soil, Aquatic Microbiology and Industrial Microbiology |
| CO5 | Control of microbial contamination during manufacture and sterility testing |
| CO6 | Analyze the role of Microbial Therapeutics |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| |
|---|
| **Unit-1: INTRODUCTION 7 hours** |
| Introduction to the scope of microbiology, Structure of bacterial cell, Classification of microbes and their taxonomy, Bacteria and viruses |
| **Unit-2: IDENTIFICATION OF MICROBES 7 hours** |
| Identification of Microbes: Stains and types of staining techniques, electron microscopy. Reproduction and Growth of Microbes, cultivation & isolation of bacteria & viruses |
| **Unit-3: CONTROL OF MICROBS 7 hours** |
| Control of microbes by physical and chemical methods, Disinfection, disinfectants and antiseptics and their evaluation, Sterilization, different methods, validation of sterilization methods & equipments |
| **Unit-4 : MICROBIAL PHYSIOLOGY AND GENETICS 7 hours** |
| Enzymes and their regulation, Microbial Metabolism: Energy Production, Bacterial Genetics, Microbiology of soil, Aquatic Microbiology, Industrial Microbiology |
| **Unit-5: MICROBIAL ASSAYS 7 hours** |
| Microbial assays of antibiotics, Factory and hospital hygiene, manufacture of sterile products, nosocomial infection, control of hospital infections, Sterility testing as per I**.P.** |
| **Unit-6: Microbial Therapeutics 5 hours** |
| Bacteria as source of antimicrobial proteins; Microbes as source of antitumor drugs; Microbes as enzyme inhibitors; Microbes as 6 mmune-suppresants etc. |

**Suggested Readings**


6. Aneja K.R. Experiments in Microbiology, Plant Pathology, Tissue Culture & Mushroom Cultivation, Vishwa Prakashan.

2. Gunasekaran P, Lab Mannual of Microbiology, New Age Publishers

3. Davis, Dulbetco, Eisen Microbiology.

4. Stanier R.Y., Ingraham, J.L., Wheelis M.L. & Painter P.R. General Microbiology, Macmillan Press Limited.

5. Hugo and Russell, Pharmaceutical Microbiology, Black Well Scientific Publication, Oxford. 6. Prescott L.M., Harley J.P. & Klien D.A. Microbiology, McGraw Hill.

7. Sykes, Disinfection and Sterilization.


| | | | | | |
|---|---|---|---|---|---|
| **Name of The** | **HUMAN PHYSIOLOGY-II** | | | | |
| **Course Code** | **BSCRT 2004** | | | | |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50 % marks in aggregate. | | | | |
| Corequisite | Basic knowledge of human physiology | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

**Course Objectives**: Students are able to understand the basic concept of Physiology and they can apply the knowledge of physiology in understanding the various diseases and keeping the body in healthy state.

**Course Outcomes**

Students are able to

| | |
|---|---|
| CO1 | Describe Structure of Neurons, action potential, Neurotransmitter |
| CO2 | Explain Mechanism of Muscle contraction in skeletal tissue |
| CO3 | Describe Structure and functional anatomy of eye and ear |
| CO4 | Explains Endocrinology including hormones and their action |
| CO5 | Explain Reproductive processes |
| CO6 | Understand the Skeletal physiology |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1 Nervous system 7 hours** |
|---|
| Nervous system: Structure of Neurons, action potential, Neurotransmitter, gross neuroanatomy of the brain and spinal cord, central and peripheral nervous system, Structure of cerebrum and function of different area of cerebral cortex, memory and cognition, Thermoregulation, mechanism of thermo sensation pathways. |
| **Unit-2 Muscle physiology 7 hours** |
| Muscle physiology: Mechanism of Muscle contraction in skeletal tissue, structural and function difference between skeletal muscle and cardiac muscle. Structure of actin and myosin filament, Tetany, muscular dystrophy. |
| **Unit-3 Sensory system 7 hours** |
| Sensory system: Functional anatomy of eye, Structure and functional anatomy of retina, Structure of rod and cone cells and their pigments, Molecular mechanism of rhodopsin, mechanism of Vision, hyperpolarization of rod receptor potential, Functional anatomy of ear; structure and function of organ of corti, Inner hair cells (IHC) and outer hair cells (OHC) stereocilia, mechanism of Hearing. Common disorders of the following sensations: Vision, Hearing, Taste, Smell and Touch |
| **Unit-4 Endocrine System 7 hours** |
| Endocrinology: Endocrine glands: Pituitary gland and hormone, thyroid gland and its hormone, adrenal gland and its hormone function, basic mechanism of hormone action, hormones and diseases. |
| **Unit-5 Female Reproductive system 7 hours** |
| Reproductive system: Reproductive processes, gametogenesis, ovulation, neuroendocrine regulation, Menstrual cycle, Hormones related to ovulation and reproductive cycle. |
| **Unit-6 Skeletal physiology 5 hours** |
| Cartilage – types with example & histology, Bone – Classification, names of bone cells, parts of long bone, microscopy of compact bone, names of bones, vertebral column, fontanelles of fetal skull, Joints – Classification with examples |

**Suggested Readings:**


1. Guyton A.C, Hall J.E, Textbook of Medical Physiology, 11th Ed., Saunders Company, 2005.
2. Widmaier E. P, Raff H, Strang K. T. Vander's, Human Physiology : The mechanism of Body Function, 9th Ed. Mc. Graw Hill, 2003.
3. Ganong W. E, Review of Medical Physiology, 21st Ed., Mc. Graw Hill, 2003.


| **Name of The Course** | **Regulatory Affairs-I** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT2005** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

Students will be exposed to Indian Drug and Cosmetic Act and Ethical Guideline

**Course Outcomes**

**On completion of this course the students will be able to understand**

| | |
|---|---|
| CO1 | Indian Good Clinical Practice Guideline for conducting Clinical Trial. |
| CO2 | Indian Drug and Cosmetic Act 1940 and New drug clinical trial rule 2019 |
| CO3 | National Ethical Guidelines For Biomedical And Health Research Involving Human Participants |
| CO4 | Investigational new drug, New Drug application and Abbreviated new drug application Submission procedure and 21 Code of Federal Regulation |
| CO5 | Informed Consent process in special Population or Vulnerable patient |
| CO6 | Analyze the Medical Device, Vaccine and Biologics Regulations |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term Test (MTE)** | **End Term Test (ETE)** | **Total Marks** |
|---|---|---|---|

| | | | |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| |
|---|
| **Unit-1: Indian Good Clinical Practice 7 hours** |
| Overview of ICH GCP, Glossary, Prerequisites for the study, Responsibilities of Sponsor, Monitor, Investigator, Statistics, Special Concern, Basic Principles for all Medical Research. |
| **Unit-2: NDCT 2019-I 7 hours** |
| Approval of new drug/Medical devices, Import of drugs/medical devices/cosmetics, Clinical trials, EC Registration, SAE Evaluation, Ammendments to Dand C Acts and rules their under, Pharmacovigilance, DTAB/DCC. |
| **Unit-3: Guidelines and Ethical Issues of Medical Research 7 hours** |
| Introduction to ICMR and centers, Statement of general principles, Human genetics testing and research, Biological materials |
| **Unit-4 : Clinical Research Regulatory Submission & Approval Process 7 hours** |
| Food and Drug Administration- Investigational new drug, New drug application and Abbreviated new drug application Submission Procedure, |
| **Unit-5: General ethical Consideration 7 hours** |
| Ethical review procedures, Informed consent process, Vulnerability, Clinical trials of drugs and other interventions, Assisted reproductive technology |
| **Unit-6: Medical Device, Vaccine and Biologics Regulations 5 hours** |
| Medical Device Regulation in India, Vaccine Regulation, Biologics Regulation, 21 CFR |

**Suggested Readings:**


1. Indian Council of Medical Research Guideline
2. Drug and Cosmetic Act 1940 Schedule Y
3. Indian Good Clinical Practice Guideline
4. Principles and Practice of Clinical research by John I, Gallin;Academic Press Inc;3rd Edition


# Semester III

| | | | | | |
|---|---|---|---|---|---|
| **Name of The Course** | **Regulatory Affairs - II** | | | | |
| **Course Code** | **BSCRT 3001** | | | | |
| **Prerequisite** | | | | | |
| **Corequisite** | | | | | |
| **Antirequisite** | | | | | |
| | **L** | **T** | **P** | **C** | |
| | **3** | **0** | **0** | **3** | |

**Course Objectives:**

The students will be familiarized with international rules and regulations pertaining to Clinical Research**.**

**Course Outcomes**

**On completion of this course the students will be able to understand**

| | |
|---|---|
| CO1 | International Conference on Hormonization Good Clinical Practice guideline |
| CO2 | Regulatory requirement in US and European Union and their different committees |
| CO3 | Regulatory requirement in Japan, Australia and Brazil |
| CO4 | Regulatory requirement for Medical Devices, Classification of medical Devices, Regulations for Biological products Trial |
| CO5 | Understand the New drug clinical trial rule -II |
| CO6 | Analyze the Common Technical Document |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term Test (MTE)** | **End Term Test (ETE)** | **Total Marks** |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| |
|---|
| **Unit-1: International conference on Hormonization Good Clinical Practice 7 hours** |
| Background of drug regulations, International Conference on Harmonization, ICH Guidelines, Principle of GCP, Ethics Committee, Investigator, |

| |
|---|
| Sponsor, Investigational Brochure, Protocol, Essential Documents. |
| **Unit-2: Regulatory Requirements in US and European Union 7 hours** |
| Food and Drug Act (USFDA), Organization structure and Functions, EU regulations, EMEA Structure and Functions, England Regulation (MHRA). |
| **Unit-3: Other Country Regulation 7 hours** |
| Australia Regulation (TGA), Japan Drug Regulation (MHLW, PMDA), Brazil Guideline (ANVISA). Investigational new drug Application :requirements forms , contents, application form, Types, Emergency use, review process, actions, Guidance documents, application procedure for ANDA filing, Basic Regulation of Bioavailability/Bioequivalence Studies |
| **Unit-4 : Medical Device and Biological product 7 hours** |
| Global Regulations for Medical Devices, Classification, Regulatory agencies and regulations, Biological products Trial, Types of Biological products, Drug Development for Orphan diseases and Drug legislation. |
| **Unit-5: New drug clinical trial rule –II 7 hours** |
| License to manufacture, sale and distribution, monitoring quality of drugs and cosmetics, Investigations and prosecution, Enforcement of DMR Act and DPCO, Joint inspection. |
| **Unit-6: Common Technical Document 5 hours** |
| Common Technical Document: Purpose , structure and contents |

**Suggested Readings:**


1. Principles and Practice of Clinical research by John I, Gallin;Academic Press Inc;3rd Edition
2. Textbook of Pharmaceutical Medicine. Edited by John. P. Griffin;Wiley Blackwell;10th Edition
3. Guidelines like GCP, USFDA, EMEA, MHRA, TGA, Indian GCP etc.
4. Good clinical practice: Consolidated guideline, ICRI
5. Basic Principles of Clinical research, S.K.Gupta, ICRI
6. MRC Guidelines for Good Clinical Practice in Clinical Trials, ICRI
7. Guidance for Investigational New Drug Applications, ICRI


| **Name of The Course** | **Drug Discovery and Development** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT 3002** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**

Students will get exposure about Drug Discovery and Development

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Drug Discovery and Development |
| CO2 | Understand about the Pre-Clinical Studies |
| CO3 | Understand about Bioassays |
| CO4 | Understand about the Drug designing |
| CO5 | Understand about the Methods and Process of Drug discovery |
| CO6 | Understand about the Non Clinical Drug Development |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Introduction to Drug development** | **7 hours** |
|---|---|
| Need for a new Drug, Target identification, lead identification, Sources of new drugs: synthetic, natural, endogenous, peptides; compounds for screening as a potential drug, Drug Discovery & Drug development process. In vivo, in vitro and in silico studies. Animal models of diseases. | |
| **Unit-2: Pre-Clinical Studies** | **7 hours** |
| Importance of Pre-Clinical studies, Steps involved in Pre-clinical studies, Types of Pre-Clinical Studies, Introduction to toxicology, Organ specific toxicity, Toxicity Studies. | |
| **Unit-3: Bioassays** | |
| Bioassays; Biochemical, Molecular, Behavioural & Physiological parameter analysis, | |

| | |
|---|---|
| Pharmacokinetics, Pharmacology, Pharmacodynemics, Tissue distribution study | |
| **Unit-4: Drug designing** | **7 hours** |
| Drug design-Ligand based, Structure based, target-centered drug design: DNA, RNA and Protein based drug designing, Structure Activity Relationship (SAR), Quantitative Structure Activity Relationship (QSAR), Computer assisted drug designing (CADD) | |
| **Unit-5: Methods and Process of Drug discovery** | **7 hours** |
| High Through Put Screening (HTS): Introduction, Advantages and Disadvantages, Uses, Methodology; Combinatorial Chemistry, methods and processes; Lead optimization techniques | |
| **Unit-6: Non Clinical Drug Development** | **5 hours** |
| GLP, GMP, GCP; submission of IND, NDA, ANDA | |

**Suggested Readings**


1 Preclinical Drug Development, Edited by Mark Rogge, David R. Taft, Second Edition, 25th Sep 2009.
2 Hill RG. Drug Discovery and Development-E-Book: Technology in Transition. Elsevier Health Sciences; 2012 Jul 20.
3 Choudhary MI, Thomsen WJ. Bioassay techniques for drug development. CRC Press; 2001 Oct 4.
4 Klebe G. Drug Design: Methodology, concepts, and mode-of-action. Heidelberg, Germany: Springer; 2013 Jul 10.
5 Armstrong JD, Hubbard RE, Farrell T, Maiguashca B, editors. Structure-based drug discovery: an overview. Royal Society of Chemistry; 2006


| **Name of The Course** | **Aspects of clinical trials operations** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT3003** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

Students will be exposed to all aspects of Clinical Trial operation.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | the Operational Introduction of Clinical Trial, Site selection, Patient recruitment and Retention |
| CO2 | Responsibility, Composition and basic function of Instituitional Ethics Committee, NABH accreditation process |
| CO3 | Clinical Trial Stakeholders, Roles & Responsibilities of Clinical Research Coordinator, Clinical Data Manager, Project Manager, LAB selection Procedure |
| CO4 | Filing of Case report form or electronic Case report form, Documentation procedure in Informed consent form |
| CO5 | Site selection procedure and Contingency planning to prepare for unexpected situations |
| CO6 | Analyze the Clinical Study Report |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term Test (MTE)** | **End Term Test (ETE)** | **Total Marks** |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content:**

| |
|---|
| **Unit-1: Operational Introduction 7 hours** |
| Site Selection parameters: Location, ICH-GCP compliance, Patient Recruitment and Retention, Single/Multi Centre Trial, Investigator Selection and agreement, Undertaking by the Investigator. |
| **Unit-2: Operation of IRB/IEC 7 hours** |
| Introduction, Defining Scope of IRB/IEC, Responsibilities, Composition of IRB/IEC, Basic Functions, NABH Accreditation of EC, EC role in Special Population Studies. |
| **Unit-3: Clinical Trial Stakeholders 7 hours** |
| Roles & Responsibilities Sponsor, Investigator, Hospital, CROs/SMOs, CRA/CRC, Auditor, Inspector, Clinical Data Manager, LAB selection Procedure, Budgeting and Contracting |
| **Unit-4 : Documentation 7 hours** |
| Investigator's Brochure, Source data verification, Study Protocol, CRF & e-CRF, ICF Process, |

| **Unit-5: Site Management 7 hours** |
|---|
| Monitoring visits, audits and inspections, Total quality Management, termination of a trial, Handling missing data, query and resolution Database lock, Site close-out report, CSR, submission to ethics committee and regulatory agency, publication of results. |
| **Unit-6: Clinical Study Report 5 hours** |
| Clinical Study Report, SOP, Essential Documents, Conflict of interest in Research, Record retention. |

**Text** Book (s)

1. Guidelines like GCP, USFDA, EMEA, Indian GCP etc.
2. Good clinical practice: Consolidated guideline, ICRI
3. White book for Clinical Research, ICRI
4. CRA handbook, ICRI
5. Basic Principles of Clinical research, S.K.Gupta, ICRI
6. Principles and practice of Clinical Research by John. I Gallin.;Academic Press;3rd Edition
7. Principles and practice of clinical trial medicine by Richard Cin and Bruce Y. Lee; Academic Press;

| **Name of The Course** | **Ethical Guidelines in Clinical Trial** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT3004** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

To understand the Ethical Guideline in Clinical Trial

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Evaluation of Ethics in clinical research, Unethical clinical trial, Kefauvers Harris amendments act, Fraud and Misconduct in clinical research |
| CO2 | ICMR Guideline, Statement of general principles, General ethical issues, Responsible conduct of research |
| CO3 | Legal Liability in Clinical Research, Legal obligations of the investigator, Compensation to subjects/patients for clinical trial related injuries |
| CO4 | Overview of IRB/IEC, Ethics review procedure and Approval, Importance of Inform Consent Document |
| CO5 | Analyze the Ethical Aspects during clinical trials of Drugs and other interventions |
| CO6 | Analyze the International Ethical Consideration in Clinical Trial |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term Test (MTE)** | **End Term Test (ETE)** | **Total Marks** |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content:**

| **Unit-1: Evolution of Ethics –I 7 hours** |
|---|
| Statement of general principles, Tuskegee experiment, Thalidomide disaster, Kefauvers Harris amendments act, Declaration of Helsinki, Belmont report, Establishment of CIOMS and NIH, Fraud and misconduct, detection of fraud in clinical research, Ethics in academia, Violations of ethics in research |
| **Unit-2: Evolution of Ethics – II 7 hours** |
| General ethical issues, Nuremberg Code, Ethical review procedures, Informed consent process, Vulnerability, Clinical trials of drugs and other interventions, Public health research, Biological materials |
| **Unit-3: Legal Liability 7 hours** |
| Legal Liability in Clinical research, negligence, strict liability, criminal liability, Legal obligations of the investigator, Compensation to subjects/patients for clinical trial related injuries |
| **Unit-4 : Overview of IRB/IEC 7 hours** |
| Definition, Composition, Role and Responsibility, Ethics review procedure and Approval, Importance of Inform Consent Document; Patient Information Sheet & Inform Consent Form |
| **Unit-5: Ethical Aspects during clinical trials of Drugs and other interventions 7 hours** |
| Phytopharmaceutical drugs, Clinical Trials with stem cells, bioavailability/Bioequivalence study, |

| |
|---|
| Radioactive materials and X ray, Surgical Interventions, Clinical Trials on traditional system of medicines, Ethical Implementation of Clinical Trial Design, Pregnancy and clinical trials, Principles of public health research ethics |
| **Unit-6: International Ethical Consideration in Clinical Trial 5 hours** |
| Standards and guidance for entities that establish research ethics committees and their members (WHO Guideline), Assisted Reproductive technologies (ICMR), Individuals capable of giving Informed Consent (WHO- CIOMS) |

**Suggested Readings:**

1. Basic Principles of Clinical Research and Methodology by S.K Gupta;Jaypee Brothers and Medical Publishers; First Edition
2. New drug clinical trial 2019- CDSCO site
3. Oxford Text Book of Clinical Research Ethics by Ezekiel J. Emanuel, Christine C. Grady, Robert A. Crouch; OUP USA; 2008 Edition

# Semester IV

| | | | | |
|---|---|---|---|---|
| **Name of The Course** | **PHARMACOLOGY – I** | | | |
| **Course Code** | **BSCRT 4001** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

This subject deals with the pharmacology of cardiac glycoside drugs e.g. digitoxin, digoxin, antianginal drugs e.g. nitrates, antihyperlipidemic drug e.g. statins, antiarrhythmic drugs e.g. lidocaine, Anticoagulants e.g. heparin, Fibrinolytics e.g. streptokinase, Antiplatelet drugs e.g. Aspirin, Antiasthmatic drugs e.g. bronchodilators, Anti-tussive drugs- opioids(codeine). It also deals with the anti-inflammatory, analgesic, antipyretic drugs and drugs used for migraine treatment e.g. NSAIDS. Drugs acting on GIT antacids- sodium bicarbonate, anti ulcer drug- cimetidine, omeprazole, antiemetics-hyoscine.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | the definition of pharmaco-therapeutics, clinical pharmacology and nomenclature related to pharmacology |
| CO2 | different routes of drug administration, rational/irrational prescribing and fixed dose combination |
| CO3 | Different dosage forms of drugs, their advantage and disadvantages |
| CO4 | principle and mechanism of drug action, factors modifying drug action |
| CO5 | the concept of ADME, bioavailability of drug, receptor and protein blinding |
| CO6 | Analyze the Novel drug delivery system |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term Test (MTE)** | **End Term Test (ETE)** | **Total Marks** |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| |
|---|
| **Unit-1 Introduction to Pharmacology 7 hours** |
| Definitions and brief, pharmaco-therapeutics, clinical pharmacology, chemotherapy, pharmacy and toxicology), drug Nomenclature (chemical name, non-proprietary name and proprietary name) and essential drugs concepts. |
| **Unit-2 Drug Administration 7 hours** |
| Route of Drug administration- Local routes (topical, deeper tissues and arterial supply etc.), Systemic routes (Oral, sublingual, rectal, cutaneous, inhalation, nasal, parenteral etc.), Novel Drug Delivery System, Sources of Drugs (Natural sources and synthetic sources). Rational prescribing, Irrational prescribing, Instruction to patients, Fixed Drug Combination: Advantages & disadvantages; Drugs used in Special Conditions. |
| **Unit-3 Dosage Forms of Drug 7 hours** |
| Definition and brief about the dosage forms – solid dosage forms (powder, tablets, capsules, lozenges, pills, cachets), liquid dosage forms (suspension, emulsion, elixirs, syrups, lotions, inhalations, eye drops, ear drops, enemas, mouth washes etc.), semisolid dosage forms (ointments, creams, pastes, gels, suppositories, etc.), sterile products |

| |
|---|
| (Injection, ophthalmic etc.), gas (aerosols, inhalations, sprays etc.) |
| **Unit-4 Pharmacodynamics 7 hours** |
| Principles of drug action and mechanism of drug action, dose response curve and adverse drug reaction, Agonists, Antagonists. Therapeutic Index Factors Modifying Drug Action, Body size, age, sex, species and race, genetics, environmental factors, psychological factor, pathological states, other drugs, cummulation, tolerance, etc |
| **Unit-5: Pharmacokinetics 7 hours** |
| Absorption, Distribution, Metabolism, excretion (ADME), Bioavailability, receptor and Protein binding, Placental and blood brain barrier |
| **Unit-6: Novel drug delivery system 5 hours** |
| Novel drug delivery system (liposome, nanosome, nanoparticles, microspheres, osmotic pumps, transdermal, implants, intrauterine devices) |

**Suggested Readings:**

**1** Tripathi K.D., *Essentials of Medical Pharmacology*, Jay Pee Publishers, New Delhi.

2. Rang M.P., Date M.M., Riter J.M., *Pharmacology*, Churchill Livingstone.

3. Katzung, B.G., *Basic & Clinical Pharmacology*, Prentice Hall, International.

4. Barar F.S.K., *Text Book of Pharmacology*, Interprint, New Delhi.

5. Satoskar & Bhandarkar, *Pharmacology & Pharmacotherapeutics*, Popular Prakashan Pvt. Ltd., Bombay

| **Name of The Course** | **Designing Clinical Trials** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT 4002** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:

Students will get exposure about the designing of clinical trial, methodology of designing and importance of designing.

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of designing & development |
| CO2 | Understand about the type of designing |
| CO3 | Understand about the designing in outcomes of clinical trials |
| CO4 | Understand about the different tools used in designing |
| CO5 | Understand about the evaluation of outcome |
| CO6 | Analyze the strategy of clinical trial design |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| | |
|---|---|
| **Unit-1: Introduction to clinical trial design** | **7 hours** |
| Overview and importance of clinical trial designing, title of study, terminologies, regulatory requirement for trial design, ethical consideration to develop clinical trial design | |
| Unit-**2: Fundamentals of clinical trial design** | **7 hours** |
| Objectives of clinical trial design, types of designs- observational, interventional, prospective, retrospective, single and multicentric, randomization, nonrandomization, crossover design, parallel design, comparative design, non-comparative design, single arm, multiple arm, appropriate hypotheses(superiority, inferiority, non-inferiority, equivalency). | |
| **Unit-3: Planning clinical trial design** | **7 hours** |
| Subject's recruitment, recruitment advertisement, and rule for subject withdrawal, eligibility of subject (inclusion and exclusion criteria), study procedure, recruitment period, treatment period, follow-up period, | |
| **Unit-4: Efficacy and safety assessment mechanisms** | **7 hours** |
| Objectives, definitions, Importance, description of efficacy methods and assessment parameters, baseline and endpoint measurements, description of safety and assessment methods, adverse event, serious adverse event, suspected adverse event, unexpected adverse event and reporting mechanisms. | |

| **Unit-5: Outcomes and analysis** | **7 hours** |
|---|---|
| Definition, scope, checklist, Scientifically sound study hypotheses, influence on design, intention to treat, subgroup analysis, interim analysis, scientific misconduct, description of access control, publication policy. | |
| **Unit-6 Strategy of clinical trial design 5 hours** | |
| Types of control groups including no control, placebo control, and active control, concomitant treatment, various way of randomization, various way of bias, blinding (open label, single blind, double blind, triple blind). | |

**Suggested Readings**


1. Guide to Clinical Trials (Volume-I &II), DCGI
2. Modules of Clinical trial methodology and management, RHE Life Science (CRO)
3. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ
4. 2. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)


| **Name of The Course** | **Basics of Pharmacovigilance** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT4003** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

Students will be exposed to Pharmacovigilance and their requirements, Adverse Drug Reaction Reporting and signal detection.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | the need and importance of Pharmacovigilance, Standard terms and terminologies in Pharmacovigilance |
| CO2 | Medical evaluation of Adverse event in Pharmacovigilance, Definitions and classification of ADRs, Detection and reporting |
| CO3 | Case Processing and Medical Dictionary, Global Perspective of Pharmacovigilance and Single Case Processing |
| CO4 | signal detection and management process, Managements and Risk Assessments & Evaluation |
| CO5 | Pharmacovigilance Laws and Guideline, PV Auditing and Inspection |
| CO6 | Analyze the Pharmacovigilance program in India |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term Test (MTE)** | **End Term Test (ETE)** | **Total Marks** |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| **Unit-1: Introduction of Pharmacovigilance 7 hours** |
|---|
| Definitions, Overview and Scope, Importance of Pharmacovigilance, Pharmacovigilance Regulations in India, WHO Drug monitoring Programme and Uppsala Monitoring centre. |
| **Unit-2: Medical Evaluation of Adverse Events In Pharmacovigilance 7 hours** |
| AE Reporting System And Form, Diagnosis And Managements of ADRs, Definitions and classification of ADRs Detection and reporting, Causality assessment, Severity and seriousness assessment |
| **Unit-3: Case Processing and Medical Dictionary 7 hours** |
| Global Perspective of Pharmacovigilance, Single Case Processing, Case Narrative Writing, Medra |
| **Unit-4 : Pharmacovigilance Reporting Database , Signal Detection , Managements And Risk Assessments & Evaluation 7 hours** |
| Quality System In PV, Expedited Reporting Criteria, PSUR & PBRER, PV Database And Signal Detection |
| **Unit-5: PV laws And Guideline 7 hours** |
| Regulatory Guideline & Laws In PV, SOPS In PV, PV Auditing And Inspection, Regulatory Aspects In PV. |
| **Unit-6: Pharmacovigilance program in India (PvPI) 5 hours** |
| Current scenario; ational pharmacovigilance program (NPP); Pharmacovigilance obligations of Indian companies with subsidiaries abroad; Role of Indian pharmaceutical companies; Formulation |

| |
|---|
| of India's pharmacovigilance guidelines: Future prospects; Proactive pharmacovigilance: The way forward in India |

**Suggested Readings**

1. Essentials of Pharmacovigilance, ICRI
2. Recommended text: An Introduction to Pharmacovigilance by Patrick Waller (2010)
3. Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics by Linda Fossatti Wood and MaryAnn Foote

| **Name of The course** | **Medical Microbiology** | | | | |
|---|---|---|---|---|---|
| **Course Code** | **BSCRT 4004** | | | | |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50 % marks in aggregate | | | | |
| Corequisite | Basic knowledge of microbiology | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

**Course Objectives**: Students are able to understand the Infections of the Gastrointestinal Tract, Respiratory system, Pyrexial Illness, Nervous System, and Sexually Transmitted Diseases and Congenital Infections

**Course Outcomes**

| | |
|---|---|
| CO1 | Interpret the Infections of the Gastrointestinal Tract. |
| CO2 | Explain the Infections of the Respiratory system. |
| CO3 | Understand the Pyrexial Illness. |
| CO4 | Examine the infections of Nervous System. |
| CO5 | Analyze the pathophysiology of Sexually Transmitted Diseases and Congenital Infections. |
| CO6 | Analyze the pathophysiology of Congenital Infections |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1 Infections of the Gastrointestinal Tract 7 hours** |
|---|
| Amoebiasis; Giardiasis and cryptosporidiosis; Intestinal infection by nematodes; Intestinal infection by cestodes (taeniasis and H.nana infection); Trematodes; Bacterial food poisoning(toxic and infective); E.coli Diarrhoea; Cholera; Bacillary dysentery; Hepatitis |
| **Unit-2 Infections of the Respiratory system 7 hours** |
| Streptococcal infections; Viral infections; Diphtheria; Whooping cough; Bacterial pneumonias (Haemophilus and GNB, Pneumococcus/Legionella/ etc); Tuberculosis, COVID-19, MERS |
| **Unit-3 Pyrexial Illness 7 hours** |
| Malaria; Kala-azar; Leishmaniasis; Filaria; Enteric fever; Brucellosis; Rickettsial diseases; Leptospirosis and relapsing fever; Viral Hemorragic fever |
| **Unit-4 Infections of the Nervous System 7 hours** |
| Viral encephalitis and Aseptic meningitis; Rabies; Cysticercosis and other CNS parasitic infections; Tetanus |
| **Unit-5 Sexually Transmitted Diseases 7 hours** |
| Herpes Simplex virus infections; HIV infection and AIDS; Chlamydial infection; Syphilis; Mycoplasma and Ureaplasma infection; Gonorrhea and other bacterial STD |
| **Unit-6 Congenital Infections 5 hours** |
| Congenital viral infections; Toxoplasmosis; Bacterial Sepsis and Meningitis |

**Suggested Readings**

1. Betty Forbes, Daniel Sahm, Alice Weinfield, Bailey-Scott's Diagnostic Microbiology, 12th Edition, Mosby. 2007.
2. 2. Gerald Collee J, Andrew G Fraser, Barrie P Marmion, Mackie and McCartney's

Practical Medical Microbiology, Elsevier. 2006.
3. 3. Elmer W Koneman et al., Koneman's, Color Atlas and Text Book of Diagnostic Microbiology, 6th Edition, Lippincott Williams and Wilkins,2005.

| **Name of The Course** | **Basic Biotechnology** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT4005** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**
The students will be familiarized with Genetics, Molecular Biology, Biotechnology and Immunology**.**

**Course Outcomes**
On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Genetic of Inheritance, interaction between traits and quantitative inheritance |
| CO2 | Molecular Biology, transcription, translation. Mutation and mutagenesis |
| CO3 | Genetic Engineering, vectors & enzymes used in recombinant technology |
| CO4 | Understanding the immunology and vaccine production |
| CO5 | Analyze the red and white biotechnology application |
| CO6 | Analyze the yellow and green biotechnology application |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term Test (MTE)** | **End Term Test (ETE)** | **Total Marks** |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content:**

| **Unit-1: Genetics 7 hours** |
|---|
| Genetics of Inheritance - Laws of inheritance, recombination and segregation of traits, segregation ratio, interaction between traits and quantitative inheritance |
| **Unit-2: Molecular Biology 7 hours** |
| Molecular Biology - The genetic material. RNA as genetic material, fidelity of DNA replication, transcription, translation. Mutation and mutagenesis. |
| **Unit-3: Genetic Engineering 7 hours** |
| Genetic Engineering - Essentials of gene manipulation, vectors & enzymes used in recombinant technology. |
| **Unit-4 : Immunology 7 hours** |
| Active, passive, Humoral and Cellular immunity; Clonal selection theory, Cells of immune system; Immunoglobulins, Haptens, Antigens and Immunogens; Monoclonal antibodies; vaccine |
| **Unit-5: Application of Biotechnology-I 7 hours** |
| Red biotechnology (Medicine & human health); White biotechnology (Industrial process involving microorganisms) |
| **Unit-6: Application of Biotechnology-II 5 hours** |
| Yellow biotechnology (Insect Biotechnology in Drug Discovery and Preclinical Research); Green biotechnology (Genetically modified crops) |

**Suggested Readings:**

1. Elements of Genetics; Phundan singh
2. Genetics: B D Singh
3. A textbook of molecular biology: 3rd edition: Mohan p arora and Himanshu Arora
4. Basic Biotechnology: B D Singh
5. Basic and Clinical Immunology: Mark Peakman and Diego Vergani

# Semester V

| **Name of The Course** | **Clinical Data Management and SAS Training** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT5001** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**
To understand the Clinical Data Management in Clinical Trial.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Introduction to CDM, Data Management team, Roles and responsibilities of key team members and sponsor |
| CO2 | CRF Design and Medical Coding, Clinical data entry process, Data entry screen validation |
| CO3 | Study setup and Guideline, Laboratory Data and Range checks, creating reports and transferring data |
| CO4 | Data Management and Discrepancy Management and Introduction to data transfer procedure |
| CO5 | SAS Training and Overiew of Argus and ORACLE |
| CO6 | Analyze the Query Management in clinical research |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content:**

| |
|---|
| **Unit-1: Introduction to Clinical Data Management and SOPs 7 hours** |
| Introduction, history and overview of CDM, Data validation, System validation, Clinical Data Management flow, Data Management team, Roles and responsibilities of key team members and sponsor, SOPs of data Management. |
| **Unit-2: CRF Design and Medical Coding 7 hours** |
| Procedure for CRF design, elements of CRF, Tracking CRF data, data base validation. Clinical data entry process, Data entry screen validation, symbols, Data Standards, Data base closure, Types of dictionaries, Clinical Data Coding and Coding Checks. |
| **Unit-3: Study setup and Guideline 7 hours** |
| Electronic Data Capture, Laboratory Data and Range checks, Data Storage and Archival, Collecting Adverse event data, Remote data entry, QA and QC, Creating reports and transferring data, Guideline and Regulation in Clinical Trial Data. |
| **Unit-4 : Data Management 7 hours** |
| Introduction to data base lock, minimum standards, procedure, Discrepancy Management, errors found after database closure, freezing, SOPs for Data management |
| **Unit-5: SAS Training 7 hours** |
| Software Training: Argus, Oracle, Recent advancement in CDM |
| **Unit-6 Query Management 5 hours** |
| Types of queries, Management of queries, SAE reconciliation. |

**Suggested Reading**


1. Society for Clinical Data Management, Good clinical Data Management Practices version 3. Sep 2003
2. Colleen M Cox. Planning the data Management Process for a clinical trial, Technology and Data Management. Monitor, Sep 2005.
3. Louis Pozzo, Glen de Vries. Applied Clinical Trials, Oct 5 2005
4. Paul Bliecher, Applied Clinical Trials, Apr 1, 2005
5. Rondel, R. Varley, S. Webb, C. Clinical Data Management. New York: John Wiley and Sons LTD. 2000


| **Name of The Course** | **PHARMACOLOGY II** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT5002** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

The basic objective of this course is to get familiar with pharmacology.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Understand the different drugs acting on central nervous system |
| CO2 | Understand the different drugs acting on autonomic nervous system |

| | |
|---|---|
| CO3 | Understand the different drugs acting on cardiovascular system |
| CO4 | Understand the Anti-hypertensive drugs and their mechanism of action |
| CO5 | Understand the Drugs acting on respiratory system |
| CO6 | Analyzing the drugs acting on Blood |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| |
|---|
| **Unit-1: Drugs acting Central Nervous System(CNS) 7 hours** |
| General anesthetics, anxiolytics and hypnotics drugs, anti depressants, CNS stimulants and psychotomimetic drugs, Opioid analgesics and opioid anatagonists, Drug dependence and drug abuse, Antiepileptic drugs, Drug therapy for neurodegenerative disorders like parkinson's disease and schizophrenia. |
| **Unit-2: Drugs acting on Autonomic Nervous System (ANS) 7 hours** |
| General introduction, Parasympathomimetic, parasympatholytic, Sympathomimetic, sympatholytic agents, Ganglionic stimulants, blockers and adrenergic neuron blocking drugs, local anesthetics |
| **Unit-3: Drugs acting on Cardiovascular System (CVS) 7 hours** |
| Cardiac glycosides and positive ionotropic agents, Anti-arrhythmic drugs, Antihypertensive drugs, Coronary vasodilators and drugs used in angina, Anti-hyperlipidemic drugs, Fibrinolytic agents, Cardioprotective agents, Anti-anginal agents. |
| **Unit-4: Antihypertensives: 7 hours** |
| Overview, classification of antihypertensive drugs- Diuretics, Sympatholytics, angiotensin inhibitors, vasodilator, dopamine agonists |
| **Unit-5: Drugs acting on Respiratory System and NSAID 7 hours** |
| Expectorants, Anti-tussive bronchodilators, Drugs used in common cold. Classification of NSAIDS, Mechanism of action, NSAIDSwhich do not inhibit prostaglandin synthesis. |
| **Unit-6: Drugs Acting on Blood 5 hours** |
| Agents used to treat anemias and haematopoietic growth factors; Coagulants and anticoagulants; Antiplatelet drugs; Fibrinolytic, antifibrinolytic, plasma expanders |

**Suggested Readings**

**1.** Tripathi, K.D., *Essentials of Medical Pharmacology*, Jay Pee Publishers, New Delhi.
2. Satoskar & Bhandarkar, *Pharmacology & Pharmacotherapeutics*, Popular Prakashan Pvt. Ltd.,Bombay.
3. Katzung, B.G., *Basic & Clinical Pharmacology*, Prentice Hall, International.
4. Rang M.P., Dale M.M., Riter J.M., *Pharmacology*, Churchill Livingstone.
5. Barar F.S.K., *Text Book of Pharmacology*, Interprint, New Delhi.
6. Kulkarni S.K., *Hand Book of Experimental Pharmacology*, Vallabh Prakashan, Delhi.

| **Name of The Course** | **Electrophysiology** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT5003** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**

To impart the complete knowledge of Electrophysiology which forms the base of Bioinstrumentation i.e. how Bioelectric signals are generated, propagated, transduced, amplified and recorded. Proper recording of the bioelectric signals help in diagnosis of the diseases.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Understanding of bioelectric phenomena |
| CO2 | Understanding of Interaction of signals |
| CO3 | Understanding of Electrical circuit model of the membrane |
| CO4 | Analyze the ECG EMG and EEG |
| CO5 | Examine the Central nervous system and neuro-control mechanisms |
| CO6 | Analyze the Receptors as biological transducers |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| |
|---|
| Unit-1: **Introduction to bioelectric phenomena 7 hours** |
| Bioelectric phenomena, Neurons and Synapse; Generation, Transmission and Propagation of signals in nervous systems – Resting Potential, Action Potential, Synaptic Potential. |
| Unit-2: **Interaction of signals 7 hours** |
| EPSP (Excitatory Post Synaptic Potentials) and IPSP (Inhibitory Post Synaptic Potentials); Interaction of signals to control various functions and reflexes of body. |
| Unit-3: **Electrical circuit model of the membrane 7 hours** |
| Electrical circuit model of the bio-membrane, The Laws of stimulation and conduction of nerve impulse. |
| Unit-4 : **ECG EMG and EEG 7 hours** |
| Electrocardiography (ECG) and its diagnostic applications– Generation and propagation of cardiac impulse, SA node as Pacemaker, Ectopic Pacemakers, PQRST Wave Pattern. Various cardiographic leads (Limb leads, Chest leads), Vectorial analysis of normal and diseased heart Electrophysiological signals- EMG, Brain potentials and their generation, Propagation, recording and diagnostic applications. |
| Unit-5: **Central nervous system and neuro-control mechanisms 7 hours** |
| Nervous system, Neuro-Anatomy in brief, Neural circuits for processing information, Central Nervous System, Peripheral Nervous System, Ventricle and Cerebrospinal Fluid, Neuro control Mechanisms |
| **Unit-6 Receptors as biological transducers 5 hours** |
| Receptors as biological transducers, Transduction and Amplification in receptors, Properties of receptors. |

**Suggested Readings:**


1. Introduction to Neurobiophysics, Vasilescu, S.G. Margineanu, Abascus Press, Tunbridge Wells, Vent.
2. Text Book of Medical Physiology, Guyton A.C. and J.E. Hall, Harcourt India Pvt. Ltd.
3. Anatomy and Physiology, Ross and Wilson, Churchill Livingstone.


| **Name of The Course** | **Hospital and Healthcare Administration** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT5004** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

The students will be familiarized with to know about Indian healthcare system: The Indian healthcare sector is expanding rapidly, with an estimated market value of US$ 280 billion by 2020.

This course will provide strategic insights and business skills for those working across the worldwide health sector.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Basic concepts of Health, Natural history of disease and role of hospitals to offer various levels of care |
| CO2 | Introduction to Hospital Management, Concepts of Healthcare industry, Department and organization structure of different types of hospitals |
| CO3 | Hospital's Department, Supportive and Ancillary service Departments |
| CO4 | Basics of Drug Management, Computerized Drug management system |
| CO5 | Procurement of Drugs, Procedure of drug indenting |
| CO6 | Analyze the Health Systems in India |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term Test (MTE)** | **End Term Test (ETE)** | **Total Marks** |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| |
|---|
| **Unit-1: Basic Concepts of Health 7 hours** |

| |
|---|
| Concept of health & disease and well-being, Prevention aspect of diseases, Dynamics of disease transmission, Changing pattern of diseases, Common pathological conditions, Basic concepts of interpretation of investigations reports |
| **Unit-2: Introduction to Hospital Management 7 hours** |
| Concepts of Healthcare industry and its ever-changing character, terminal planning, design and operation, Concept of hospitals, space required for separate functions, overview, design & planning of different types of hospitals, Problems and constraints in hospitals. |
| **Unit-3: Deparmentation in Hospital 6 hours** |
| Organization, Structure, Vertical and Horizontal, Clinical and Non- Clinical, Supportive and Ancillary service Departments, Department and organization structure of different types of hospitals. |
| **Unit-4 : Basics of Drug Management 7 hours** |
| Drug Management, Hospital Pharmacy License and Drug License, Narcotics drug storage, Pharmacy billings, Computerized Drug management system, Rational use of Drugs and Prescription Audits, Spurious Drugs, Banned Drugs |
| **Unit-5: Procurement of Drugs 6 hours** |
| Purchase of drugs and other consumable materials, Procedure of drug indenting, On time drug dispensing inventory control, Methods of ordering – two bin system (lead time, buffer stock, reorder level) cyclic system |
| Unit-6 **Health Systems in India 7 hours** |
| Health planning in India including various committees and National Health Policy and Health Goals set from time to time. Organised sector with reference to Centre, State, District and Block level structures and local bodies and Panchayati Raj Organisation and functions of community health centres and Primary Health Centres (PHCs). Health Manpower, Primary Health care and concept, Alternative systems of medicine, like Ayurveda, Homeopathy, etc. Holistic Approach Non-Governmental Organisations (NGOs) and Private Voluntary Organisations (PVOs). Unorganized Sector |

**Suggested Readings:**

**1.** Hospital Management: Principle, Theory and Practice by Amit Virmani

2. Hospital Management: An Evaluation – by A.K. Malhotra

3. Principles of Hospital Administration & Planning: B.M. Sakharkar (Jaypee)

| **Name of The Course** | **Clinical trial amended rule** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT 5005** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Objectives:**

The basic objective of this course is to get familiar with new drug clinical trial rule 2019.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Introduction to CDSCO structure and organogram |
| CO2 | Chapter 1 to Chapter 6 of NDCT 2019 |
| CO3 | Chapter 7 to Chapter 13 of NDCT 2019 |
| CO4 | Rule 1 to rule 107 of NDCT 2019 |
| CO5 | Schedule 1 to schedule 8 of NDCT 2019 |
| CO6 | Form 1 to form 27 of NDCT 2019 |

**Course Content**

| |
|---|
| Unit-1: CDSCO Structure and Organogram<br>7 hours |
| Central licensing authority (CLA), State licensing Authority (SLA), Schedule 1 and Schedule 2 |
| Unit-2: Chapter Part-I<br>7 hours |
| Chapter 1 to chapter 6 |
| Unit-3: Chapter Part-II<br>7 hours |
| Chapter 7 to chapter 13 |

| |
|---|
| Unit-4: Rules (NDCT 2019)<br>7 hours |
| Rules 1 to rules 107 |
| Unit-5 : Schedules (NDCT 2019)<br>7 hours |
| Schedule 1 to schedule 8 |
| Unit-6: Forms (NDCT 2019)<br>5 hours |
| Form 1 to form 27 |

**Suggested Readings:**

NDCT 2019 (https://cdsco.gov.in/opencms/opencms/Pdf-documents/NewDrugs_CTRules_2019.pdf)

| **Name of The Course** | **Molecular Diagnostics & Therapeutics** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT 5006** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:

Students will understand about the tools and techniques used in the molecular diagnosis & Therapeutics.

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the basic concepts of host pathogen interactions and Biomarkers |
| CO2 | Understand the biochemical based diagnosis. |
| CO3 | Understand the DNA based diagnosis |
| CO4 | Understand the protein based diagnosis |
| CO5 | Understand the Cellular therapy |
| CO6 | Understand about the Recombinant therapy & Immunotherapy |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Host pathogen interactions and Biomarkers** | **7 hours** |
|---|---|
| Biomarkers- types and applications; Host pathogen interactions in disease process; Protective immune response in Bacterial, Viral and Parasitic diseases; Cancer; Inappropriate Immune response; Disease pathology and clinical spectrum; Clinical diagnosis of diseases; Molecular Genetics of the host and the pathogen | |
| **Unit-2: Biochemical based diagnosis** | **7 hours** |
| Biochemical disorders; Molecular techniques for analysis of these disorders; Assays for the Diagnosis of inherited diseases; Antibody based diagnosis; Monoclonal antibodies as diagnostic reagents; Production of monoclonal antibodies with potential for diagnosis; Diagnosis of bacterial, viral and parasitic diseases by using; ELISA and Western blot. | |
| **Unit-3: DNA based diagnosis** | **7 hours** |
| Aptamers; DNA sequencing and diagnosis; PCR and Array based techniques in diagnosis; Single nucleotide polymorphism and disease association; Two dimensional gene scanning. | |
| **Unit-4: Protein based diagnosis 5 hours** | |
| Protein Micro array; Present methods for diagnosis of Specific diseases like Tuberculosis, Malaria and AIDS; Ethics in Molecular Diagnosis | |
| **Unit-5: Cellular therapy** | **7 hours** |
| Cellular therapy; Stem cells: definition, properties and potency of stem cells; Sources: embryonic and adult stem cells; Concept of tissue engineering; Role of scaffolds; Role of growth factors; Role of adult and embryonic stem cells; Clinical applications; Ethical issues | |
| **Unit-6: Recombinant therapy & Immunotherapy** | **7 hours** |
| Recombinant therapy; Clinical applications of recombinant technology; Erythropoietin; Insulin analogs and its role in diabetes; Recombinant human growth hormone; Streptokinase and urokinase in thrombosis; Recombinant coagulation factors; Immunotherapy; Monoclonal antibodies and their role in cancer; Role of recombinant interferons; Immunostimulants; Immunosupressors in organ transplants; Role of cytokine therapy in cancers; Vaccines: types, recombinant vaccines and clinical applications | |

**Suggested Readings:**

1. Campbell, M.A and Heyer L.J., Discovering Genomics, Proteomics and Bioinformatics, 2nd Edition, CSHL Press, Pearson/Benzamin Cummings San Francisco, USA, 2007.
2. Andrew Read and Dian Donnai, New Clinical Genetics, Scion Publishing Ltd, Oxfordshire, UK, 2007.
3. James W Goding, Monoclonal antibodies: Principles and Practice, 3rd Edition, Academic Press, 1996.
4. Bernhard Palsson and Sangeeta N Bhatia, Tissue Engineering, 2nd Edition, Prentice Hall, 2004.
5. George Patrinos and Wilhelm Ansorage, Molecular Diagnostics, 1 st Edition, Academic Press, 2005.
6. Lela Buchingham and Maribeth L Flawsm, Molecular Diagnostics: Fundamentals, Methods and Clinical Applications, 1 st Edition, F A Davis Company, Philadelphia, USA, 2007.


# Elective

| **Name of The Course** | **Medical Writing** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT5007** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

1) Creating documents for medical records & reference retrieval
2) To understand the different aspects of medical writing

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Importance of Medical Writing in Clinical Trial, Letter writing for editorial process, Reviewing, editing and publishing |
| CO2 | Writing Article, Research report and paper writing, systematic review |
| CO3 | Software for medical writing, Literature search and Pubmed search, Meta analysis |
| CO4 | Documents in Clinical Research, Designing and development of clinical research documents |
| CO5 | Guidelines for medical writing, Guidelines and Checklists of relevant to medical writing in diverse medical fraternities |
| CO6 | Analyze the Development of medical writing in India |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term Test (MTE)** | **End Term Test (ETE)** | **Total Marks** |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| **Unit-1: Introduction to Medical Writing 7 hours** |
|---|
| Introduction, exercises and examples, Good Publication Practices, Overview of scientific articles, Reviews, Research and submission, journal and selection, Letter writing for editorial process |
| **Unit-2: Fundamentals of Manuscript 7 hours** |
| Basic introduction to medical terminology and fundamentals of medical writing, Literature survey-Use of books and journals and internet, Research report and paper writing, systematic review, Patient narrative preparation |
| **Unit-3: Software application in medical writing 7 hours** |
| Introduction to Software, Objective, Scope, article writing and plagiarism software, Literature search and search engine, analytical tools |
| **Unit-4 : Documentation and Development 7 hours** |
| Clinical study report, Designing and development of clinical research documents i.e. protocol, ICF, CRF, SOP on various functional clinical trial procedures, Pharmacovigilance writing: ICSR, SAE reporting, Narratives, PSUR, DSUR, etc. |
| **Unit-5: Guidelines 7 hours** |
| Duties of Author and disputes, Publication policy, Editor, Reviewer, Common technical document (CTD), dossier writing, ICMJE and other bodies, Checklists, Ethical consideration, Journal quality and impact assessment and Citation |
| **Unit-6: Development of medical writing in India 5 hours** |
| The history of medical writing in India; medical writing in India—the current scenario; challenges in medical writing and possible solutions |

**Suggested Readings:**


1. Guidelines for Reporting Health Research by David Moher Doughlas Altman BMJ books; August 2014
2. Medical Writing: A Guide for Clinicians, Educators, and Researchers Second Edition; Springer 2011
3. Medical writing a good practice guide by Justina-Orleans;WileyBlackwell 2012
4. Asher R. How to present your article. BMJ, 2: 502, 1958.
5. Stephen Lock Thornes's better medical writing, Pitmen Medical, 2nd Ed. 6. 1977.
6. Fraser HS. Writing a scientific paper. West Indian Med J; 44 (4): 114-24, 1995.


| **Name of The Course** | **Clinical Trial Management** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT5008** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

Students will get exposure on Clinical Trial start up process that includes budgeting, vendor selection, Project Milestone and documentation management.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | the introduction and importance of Clinical Trial study start up process and procedure |
| CO2 | Methodology of clinical trial operation and Monitoring process |
| CO3 | Clinical trial audit |
| CO4 | Understand about the basic concepts of project mile stones and their management |
| CO5 | about checklist of budgeting, types of Cost, payment planning and controls and vendor selection |
| CO6 | Analyze the Feasibility of project, regulatory aspects, documents before the clinical trial commence. |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term** | **End Term** | **Total Marks** |
|---|---|---|---|
| | **Test (MTE)** | **Test (ETE)** | |
| **20** | **30** | **50** | **100** |

**Course Content**

| **Unit-1: Study Start up Process 7 hours** |
|---|
| Introduction, Definition, Project Kick off Meeting, Vendors selection, Duties delegation, Formation of team, Site selection, Investigator selection Procedure and requirement, Data Management handling, Selection of Lab, IP Management |
| **Unit-2: Clinical Trial Monitoring 7 hours** |
| Overall objectives, Importance, personnel, types of monitoring, pre-study, initiation study, Routine Monitoring Visit, close-out visits and their purpose, checklist, monitoring report, procedure, |
| **Unit- 3: Clinical trial audit 5 hours** |
| Clinical trial audit, type of audit, purpose of audit. |
| **Unit-4: Overview of Project mile stones and Management 7 hours** |
| Overview of project, mile stones, planning, scope, checklist, terminologies & definitions used in clinical research project management, project forecast. |
| **Unit-5 : Budgeting and outsourcing of Clinical Research Project 7 hours** |
| Objectives and scope, definition and types of costs, procedures and checklist, terminologies, specific item, agreements, payment planning and controls, cost measures, Insurance, complexity, Indemnification, Outsourcing |
| **Unit-6: Clinical Trial Documents and development 7 hours** |
| Introduction, Essential clinical trial documents, development, regulatory aspects, documents before the clinical trial commence, during clinical trial conduct and post-trial or termination of the trial, forms, logs, Patient diary, source document, questionnaires. |

**Suggested Readings**


**1.** Guide to Clinical Trials (Volume-I &II), ICRI

2. LachmanL, Liberman H.A and Kanig J.L., "Theory and Practice of Industrial Pharmacy", Lea and Febiger.

3. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ
4. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)

| **Name of The Course** | **Bioethics and Biosafety** | | | |
|---|---|---|---|---|
| **Course Code** | **BSCRT5009** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**
To understand the Bioethics and Biosafety

**Course Outcomes**
On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Understand the Conceptual foundations of biomedical ethics |
| CO2 | Analyze the Ethics in health care |
| CO3 | Examine the Ethical dimensions of GMO & Bioweapons |
| CO4 | Understand the Biosafety regulations and competent authorities |
| CO5 | Analyze the Principles and components of containment |
| CO6 | Examine the Operational Guides on Containment |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term Test (MTE)** | **End Term Test (ETE)** | **Total Marks** |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| **Unit-1 Conceptual foundations of biomedical ethics 7 hours** |
|---|
| Principlism; Deontology; Consequentialism/Utilitarianism; Communitarianism; Virtue ethics; Ethics of Care; Human Rights |
| **Unit-2 Ethics in health care 7 hours** |
| Ethical dimensions of palliative care and end-of-life care; Reproductive health ethics; Ethical issues in global health; Ethics and the pharmaceutical industry; Ethical issues in rural health care |
| **Unit-3 Ethical dimensions of GMO & Bioweapons 7 hours** |
| Ethical dimensions of genetic and genome-based research; Ethical dimensions of research involving bioweapons; Ethics in gene therapy, germ line, somatic, embryonic and adult stem cell research. |
| **Unit-4 Biosafety regulations and competent authorities 7 hours** |
| Recombinant DNA Advisory Committee (RDAC); Review Committee on Genetic Manipulation (RCGM); Institutional Biosafety Committee (IBSC); Genetic Engineering Appraisal Committee (GEAC); State Biotechnology Co-ordination Committee (SBCC); District Level Committee (DLC) |
| **Unit -5 Principles and components of containment 5 hours** |
| Factors in Containment: Physical Containment; Biological Containment; Laboratory Monitoring; Health and Medical Surveillance; Decontamination and Disposal; Emergency Procedures; |
| **Unit -6 Operational Guides on Containment 7 hours** |
| Microbiological Biosafety Level (BSL) Facilities; Containment For Large Scale Operations Of Genetically Engineered (GE) Microorganisms; Animal Biosafety Level Facilities; Containment requirement for import, export and exchange |

**Suggested Readings:**

1. Beier, F.K., Crespi, R.S. and Straus, T. Biotechnology and Patent protection-Oxford and IBH Publishing Co. New Delhi
2. Bioethics and Biosafety- M.K. Sateesh
3. Bioethics and Biosafety- Rajmohan

| **Name of The Course** | **Clinical project and dissertation** |
|---|---|
| **Course Code** | **BSCRP6051** |
| Prerequisite | |

| | | | | | |
|---|---|---|---|---|---|
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 0 | 0 | 28 | 14 |

**Course Objectives:**
Students will get exposure of Project work execution in the area of Clinical Research.

Course Outcomes

**On completion of this course the students will be able to**

| | |
|---|---|
| CO1 | Formulate questions and to discover feasible solutions |
| CO2 | Demonstrate individual initiative or group responsibility |
| CO3 | Use resource materials to express ideas and talents |
| CO4 | Design and execute the project work |
| CO5 | Report the project work in terms of thesis |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **60** | **00** | **240** | **300** |

**Course Content**

| **Unit-1: Clinical trial Project** |
|---|
| Six components are required for project completion: 1.Self-Management component<br>2. Written component 3. Research component 4. Oral component 5. Technological component 6. Visual component<br><br>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. Students will also be exposed to ongoing clinical research activities viz., different Phases of CTs, bioavailability (BE) and bioequivalence (BE) studies, pharmacokinetics, pharmacodynamics, monitoring and audit of CTs, data management, drug regulatory activities and statistical software used in clinical research |

GALGOTIAS UNIVERSITY

(Established under Galgotias University Uttar Pradesh Act No. 14 of 2011)

# Program: M.Sc Clinical Research

**Scheme: 2020-2021**

**Vision: To be known globally for education, innovation and interdisciplinary research in Biosciences, Healthcare and Biomedical Engineering**

**Mission:**

**M1**. To establish the centre of excellence in Healthcare & Clinical research.

**M2**. To establish state-of-the-art facilities of Clinical research for world class education and research.

**M3**. To conduct the multidisciplinary research in collaboration with national and international organization for developing the innovative solutions of unsolved health problems.

**M4**. To develop clinical research leaders having regulatory and ethical mind set with capability of creating value in clinical research industry.

## Program Educational Objectives:

**PEO 1.** Graduates shall conduct the clinical trials, research in healthcare and interdisciplinary field efficiently and ethically.

**PEO 2**. Graduates of clinical research shall excel in higher studies and interdisciplinary research exhibiting global competitiveness.

**PEO 3**. Graduates have a high sense of medical responsibilities and ethical thinking and solve new/unsolved/unmet medical need.

## Program Specific Objectives

**PSO1**. Evaluate critical domestic and global regulatory and health care issues that challenge and influence biopharmaceutical product development

**PSO2**. Demonstrate competencies in performing the clinical research; evaluating, analysing and presenting the clinical research results.

**PSO3**. Effectively communicate and collaborate with health care providers and regulatory agencies to develop culturally diverse domestic and global strategies for biopharmaceutical product approvals

**PSO4**. Demonstrate regulations, social and ethical values required to make a global clinical research professional responsible in their career.

## Program Outcomes

**PO1- Clinical Research Knowledge**: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of clinical Research, including regulatory guidelines, Drug Development and Drug safety, Ethical aspects in Clinical Research, Pharmacovigilance and Sponsor, Hospital and Investigator responsibilities in clinical trial, Bioavailability and Bioequivalence studies.

**PO2- Planning Abilities**: Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

**PO3- Problem analysis**: Utilize the principles of Analytical thinking, clearly and critically, while solving problems and making decisions during clinical trials. Find, analyse, evaluate and apply information systematically and making decisions related to clinical trial.

**PO4- Modern tool usage**: Learn and apply modern and appropriate tools related to clinical research. As example, Drug Designing, Statistical Analytical System (SAS), Clinical Oracle and ARGUS and Pharmacokinetic software's.

**PO5- Leadership skills**: Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfilment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles during the conduction of clinical trial to facilitate improvement in health and wellbeing.

**PO6- Professional Identity**: Understand, analyse and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, Clinical Researcher, managers, employers, employees)

**PO7- Clinical Research Ethics:** Honour human values and apply ethical principles in professional and social contexts. Demonstrate behaviour that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions during the conduction of clinical trial and selection of the volunteers.

**PO8- Communication:** Communicate effectively with the Clinical research community (healthcare provider, doctor and patient and write effective reports, make effective presentations and documentation, and give and receive clear instructions.

**PO9- The clinical research and society**: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the Clinical Research practice.

**PO10- Environment and sustainability**: Understand the impact of the Clinical research solution in societal and environmental contexts, demonstrate the knowledge of, and need for sustainable development.

**PO11- Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-access and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

## Curriculum

| Semester 1 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sl. No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | MSCRT1001 | Clinical Research Overview | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | MSCRT1002 | Pharmacology-1 | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | MSCRT1003 | Research methodology and Biostatistics | 4 | 0 | 0 | 4 | 20 | 30 | 50 |
| 4 | | Disruptive technologies | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 5 | | Professional communication | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | | Environmental Studies | 0 | 0 | **1** | 0.5 | 50 | -- | 50 |
| 7 | | Campus to corporate | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 8 | | Ethics and Professional Competency | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 9 | | Creative / Liberal Arts | 0 | 0 | **1** | 0.5 | 50 | -- | 50 |
| 10 | | Waste management | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 11 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **21** | **0** | **2** | **22** | **180** | **550** | **1100** |
| **Semester II** | | | | | | | | | |
| **Sl No** | **Course Code** | **Name of the Course** | | | | | **Assessment Pattern** | | |
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| 1 | MSCRT2001 | Regulatory affairs and Ethics in Clinical Research | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | MSCRT2002 | Pharmacology-II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | MSCRT2003 | Pharmacovigilance | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | MSCRT2004 | Drug Discovery and Development | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | MSCRT2005 | Global Regulation | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | MSCRP2051 | Clinical Research Lab-I | 0 | 0 | **4** | 2 | 50 | -- | 50 |
| 7 | | Professional communication | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 8 | | Foreign Language | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 9 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **21** | **0** | **4** | **23** | **210** | **240** | **450** |
| **Semester III** | | | | | | | | | |
| **Sl No** | **Course Code** | **Name of the Course** | | | | | **Assessment Pattern** | | |
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| 1 | MSCRT3001 | Clinical Trial and Data Management | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | MSCRT3002 | Electrophysiology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | MSCRT3003 | Operational aspects of clinical research | 4 | 0 | 0 | 4 | 20 | 30 | 50 |
| 4 | MSCRT3004 | Clinical trial amended rule | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | MSCRP3051 | Clinical Research Lab-II | 0 | 0 | **4** | 2 | 50 | -- | 50 |
| 6 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| **7** | | Disaster Management | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| **8** | | AI and its application | 0 | 0 | **4** | 2 | 50 | -- | 50 |
| **9** | | Creativity, Innovation, entrepreneurship and IPR | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **17** | **0** | **8** | **21** | **240** | **210** | **450** |

| Semester IV | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sl No** | **Course Code** | **Name of the Course** | | | | | **Assessment Pattern** | | |
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| **1** | MSCRP4051 | Clinical project and dissertation | 0 | 0 | 28 | 14 | 60 | -- | 240 |
| | | **Total** | **0** | **0** | **28** | **14** | **60** | **--** | **240** |

Detailed Syllabus

## Semester I

| Name of The Course | **CLINICAL RESEARCH OVERVIEW** | | | |
|---|---|---|---|---|
| Course Code | **MSCRT1001** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**
Students will get exposure about the need and scope of clinical research and the areas of clinical research. They will learn about different phases of clinical research.

**Course Outcomes**

| | |
|---|---|
| CO1 | Understand about basic concepts of Clinical Research. |
| CO2 | understand the historical perspective of clinical research |
| CO3 | understand different phases and types of clinical Trials |
| CO4 | Perform Intellectual property rights with major emphasis on patents for protection of IP |
| CO5 | Understand about the bioequivalence and bioavailability (BA/BE) studies. |
| CO6 | Analyzing Patent procedure in india |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| Unit-1: Introduction 7 hours |
|---|
| Definition of Clinical research, Terminologies & definitions used in Clinical Research, Difference between Clinical Research and Clinical practice, Glossary of GCP. Historical Aspects of clinical research, Brief description of different phases, Stakeholders in clinical research, Need and scope of clinical research, Areas of clinical research, career opportunities in clinical research |
| Unit-2: The Historical Prospective of Clinical Research 7 hours |
| A Brief History of Clinical Research, Sulphanilamide Tragedy, Thalidomide Disaster, Nazi Experiments, Tuskegee Study, Belmont Report, Nuremberg Code, Declaration of Helsinki Principles, ICH guidelines History, Structure, Process. |
| Unit-3: Types and Phases of Clinical Trial 7 hours |
| Introduction to Clinical Trials –Types of Clinical Trial – Randomized trial, open label study double blind, single blind, matched pair study, cross over trial, case control study, cohort study, equivalence trials, superiority trials and non-inferiority trials<br>Phases of developmental clinical trials, Phase 0, Phase I-IV<br><br>Phase I –aims of phase I – selection of volunteers-informed consent-protocol –design of study;<br>Phase II- Therapeutic exploratory, objectives of phase II; Phase Iia; Phase Iib; its regulatory requirements.<br>Phase III- Therapeutics confirmatory – Objectives of phase III- design of Phase III, protocol-regulatory requirements;<br>Phase IV – purpose, types, study design for observational studies, PMS<br>Placebo response, advantage and disadvantages of Placebo |
| Unit-4: Pharmaceutical Industry and Globalization 7 hours |
| Overview, Opportunities & Career options in Clinical Research, Overview of global and local players, what are the advantages of conducting Clinical Research in India. Intellectual Property Rights: Introduction, Scope, Objectives of IPR in pharmacy, Indian legal system & its role in IPR; Concept of property with respect to intellectual creativity; Tangible & Intangible property, concept of IPR |
| Unit-5: BA/BE Studies 7 hours |
| Bioavailability and Bioequivalence – Definition, Needs, Methods and Procedures, factors affecting Bioavailability Bioequivalence/ Therapeutic Equivalence, Study parameters: Tmax, Cmax, AUC, t1/2, Test method to assess Bioequivalence, Steady State studies, regulatory requirements, planning & design, Protocol/ CRF outline, QA & QC, Drug accountability, Elements of BE study, Facilities for conducting BA-BE study |

| Unit-6: Patent 5 hours |
|---|
| Scope & nature of patents, copyrights, trade mark, geographical limitations; Indian Patent Act 1970, Patenting in India & abroad, practical aspects of patent filing, components of a patent application in India. |

**Suggested Readings:**


1. Guide to Clinical Trials (Volume-I &II), ICRI
2. LachmanL,Liberman H.A and Kanig J.L., "Theory and Practice of Industrial Pharmacy", Lea and Febiger.
3. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ
4. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)


| Name of The Course | **Pharmacology –I Theory (40 Hours)** | | | |
|---|---|---|---|---|
| Course Code | **MSCRT1002** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:

Students will get exposure about the need and scope of clinical research and the areas of clinical research. They will learn about different phases of clinical research.

**Course Outcomes**

| | |
|---|---|
| CO1 | the definition of pharmaco-therapeutics, clinical pharmacology and nomenclature related to pharmacology |
| CO2 | different routes of drug administration, rational/irrational prescribing and fixed dose combination |
| CO3 | Different dosage forms of drugs, their advantage and disadvantages |
| CO4 | principle and mechanism of drug action, factors modifying drug action |
| CO5 | the concept of ADME, bioavailability of drug, receptor and protein blinding |
| CO6 | Analyze the Novel drug delivery system |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| Unit-1 Introduction to Pharmacology 7 hours |
|---|
| Definitions and brief, pharmaco-therapeutics, clinical pharmacology, chemotherapy, pharmacy and toxicology), drug Nomenclature (chemical name, non-proprietary name and proprietary name) and essential drugs concepts. |
| Unit-2 Drug Administration 7 hours |
| Route of Drug administration- Local routes (topical, deeper tissues and arterial supply etc.), Systemic routes (Oral, sublingual, rectal, cutaneous, inhalation, nasal, parenteral etc.), Novel Drug Delivery System, Sources of Drugs (Natural sources and synthetic sources). Rational prescribing, Irrational prescribing, Instruction to patients, Fixed Drug Combination: Advantages & disadvantages; Drugs used in Special Conditions. |
| Unit-3 Dosage Forms of Drug 7 hours |
| Definition and brief about the dosage forms – solid dosage forms (powder, tablets, capsules, lozenges, pills, cachets), liquid dosage forms (suspension, emulsion, elixirs, syrups, lotions, inhalations, eye drops, ear drops, enemas, mouth washes etc.), semisolid dosage forms (ointments, creams, pastes, gels, suppositories, etc.), sterile products (Injection, ophthalmic etc.), gas (aerosols, inhalations, sprays etc.) |
| Unit-4 Pharmacodynamics 7 hours |
| Principles of drug action and mechanism of drug action, dose response curve and adverse drug reaction, Agonists, Antagonists. Therapeutic Index Factors Modifying Drug Action, Body size, age, sex, species and race, genetics, environmental factors, psychological factor, pathological states, other drugs, cummulation, tolerance, etc |
| Unit-5: Pharmacokinetics 7 hours |
| Absorption, Distribution, Metabolism, excretion (ADME), Bioavailability, receptor and Protein binding, Placental and blood brain barrier |

| Unit-6: Novel drug delivery system 5 hours |
|---|
| Novel drug delivery system (liposome, nanosome, nanoparticles, microspheres, osmotic pumps, transdermal, implants, intrauterine devices) |

**Suggested Readings:**

1. Color Atlas of Pharmacology Ebooks by Heinz Lullmann, Kaus Mohr, Luts Hein,
2. Basic and Clinical Pharmacology by Katzung B
3. Pharmaceutical dosage form, YS Tawanr, AS Sharma
4. Elements of Pharmacology by Dr Ramesh Goyal, Dr. Anita Mehta

| Name of The Course | **Research Methodology & Biostatistics** | | | |
|---|---|---|---|---|
| Course Code | **MSCRT1003** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 4 | 0 | 0 | 4 |

**Course Objectives:**

Students will get exposure about Research Methodology

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Research |
| CO2 | Understand about the Research Design |
| CO3 | Understand about the Research Report and ethics |
| CO4 | Understand about the Sampling methods |
| CO5 | Understand about the Measures of central tendency |
| CO6 | Understand about Hypothesis testing |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**:

| Unit-1: Introduction to Research | 8 hours |
|---|---|
| Research definition, types, advantage and significance. Introduction to research methods, identifying research problem, definition, objectives, role, scope in biotech research, process of research, limitations & types | |
| Unit-2: Research Design | 7 hours |
| Concept of Interdisciplinary Research, Procedures in research. Types of Research Design: Experimental/Interventional research, Quasi-experimental studies, Observational research. Sources of Experimental Errors. Survey research: Types of surveys- CATI, CAPI, Mail, Email, Face-to-face, Questionnaire | |
| Unit-3: Research Report and ethics | 5 hours |
| Type of research report- Research, review, case report, manuscript, monograph, book chapters. Structure of Research Reports. Quoting of reference and bibliography using reference management tools. Ethical issues in research, plagiarism. | |
| Unit-4: Sampling methods | 5 hours |
| Sampling methods, Advantages and Limitation, Sampling process, Types of Sampling, Probability and Non Probability sampling techniques, sampling errors, Data collection Primary and secondary data, Collection and validation. | |
| Unit-5: Measures of central tendency | 8 hours |
| Measures of central tendency- Mean, Median, Mode; Measures of dispersion- Range, Mean deviation and Coefficient of variation, Standard deviation, Standard error; Correlation and regression; Statistical inference- Hypothesis testing, Significance level, Confidence interval, t-test, z-test. Test of significance for large and small samples; Parametric tests; Non parametric tests; Experimental design, Use of biostatistic softwares. | |
| Unit-6: Hypothesis testing | 7 hours |
| Null hypothesis and test of significance (t-test, paired t-test, Analysis of variance, Analysis of covariance, Coefficient of Variation, chi-square test, Fischer exact, Mann-Whitney, Wilcoxin, McNeman test, Kruskal Wallis. | |

**Suggested Readings**:


5. Graziano AM, Raulin ML. Research methods: A process of inquiry. HarperCollins College Publishers; 1993.
6. C.R. Kothari : Research Methodology, New Age International Publishers
7. Bouma GD, Ling R, Wilkinson L. The research process. Oxford: Oxford University Press; 1993 Mar 30.
8. Dawson B, Trapp RG. Basic and clinical biostatistics. Singapore. 2004;2001:141-2.

# Semester II

| Name of The Course | **Regulatory Affairs and Ethics in Clinical Research** | | | |
|---|---|---|---|---|
| Course Code | **MSCRT2001** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:
Students will get exposure about the ethical concepts clinical research and the process of evolution of regulatory control in clinical trial

**Course Outcomes**

| | |
|---|---|
| CO1 | about the ethical aspects important to sound clinical research |
| CO2 | importance of IRB/IEC, Independent Ethic committees, Ethic review |
| CO3 | Understand the operational imperatives of Good Clinical Practices |
| CO4 | Evolution of regulatory control, ICH-GCP, ICMR requirement |
| CO5 | international regulatory bodies and guidelines |
| CO6 | Analyze the procedure of IND and NDA |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| Unit-1: Ethic in clinical research<br>7 hours |
| Evolution of ethic 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 a investigator, compensation to subjects/patients for clinical trial related injuries |
| Unit-2; Overview of IRB/IEC/ERB<br>7 hours |
| Independent Ethic committees, Ethic review procedures, importance of inform consent document, patient information sheet, and inform consent form, Fraud and misconduct, detection of fraud in clinical research. Ethics in academia, violation of ethic in clinical research, HIPAA |
| Unit-3: Evolution of regulatory control<br>7 hours |
| Evolution of regulatory control: An international comparison, Pure food and drug act, drug and cosmetic act 1945, thalidomide disaster, Kafauvers Harris amendment act, Waxman hatch act,<br>Evolution of ICH, NICE. Introduction to ICH-International<br>Conference on Harmonization of technical requirements for registration of<br>Pharmaceuticals for human use guidelines Milestones in the evaluation of GCP |
| Unit-4: Applicable GCP Guidelines,<br>7 hours |
| International Conference on Harmonization of technical requirements for registration of Pharmaceuticals for human use guidelines (ICH-GCP), Indian Council Of Medical Research-Ethical Guidelines for Biomedical Research on Human participants (ICMR), Indian Good Clinical Practices<br>IND Application :requirements forms , contents, application , |
| Unit-5: International Regulatory bodies and Guidelines:<br>7 hours |
| **US Food and Drug Administration(USFDA)**: 21CFR 50,316,314The FDA and Food Drug and Cosmetics Act, New drug development and approval: the principal steps. **India**: Regulatory laws, Schedule Y, registration of new drugs, requirements for registration, regulatory environment and practices, Indian GCP, CTRI; **Medicines and Healthcare Products Regulatory Agency** (MHRA): Overview of regulatory environment/ background, regulatory authorities, regulatory requirements<br>and procedures. **European Agency for Evaluation of medicinal Products(EMEA):** National<br>registration , the decentralized procedures, mutual recognition procedures. Brazil: Overview of regulatory affairs. |
| Unit-6: IND and NDA<br>5 hours |
| Investigator IND, Treatment IND , Emergency use of IND. NDA application: contents , forms , review process, actions, Guidance documents for |

| |
|---|
| IND and NDA, Common Technical Document: Purpose , structure and contents |

**Suggested Readings:**

1. Guide to Clinical Trials (Volume-I &II), ICRI
2. Guideline for Drug Regulatory Submissions by Sandy Welnberg
3. International Pharmaceutical Registration by Alan A Chalmers
4. Good Clinical Practice by Josef Kolman, Paul Meng

| | | | | |
|---|---|---|---|---|
| Name of The Course | **Pharmacology –II** | | | |
| Course Code | **MSCRT2002** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**
Students will get exposure about the drugs and their mechanism of action acting on different body organ system

**Course Outcomes**

| | |
|---|---|
| CO1 | Understand the different drugs acting on central nervous system |
| CO2 | Understand the different drugs acting on autonomic nervous system |
| CO3 | Understand the different drugs acting on cardiovascular system |
| CO4 | Understand the Anti-hypertensive drugs and their mechanism of action |
| CO5 | Understand the Drugs acting on respiratory system |
| CO6 | Analyzing the drugs acting on Blood |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| **Unit-1: Drugs acting Central Nervous System(CNS) 7 hours** |
| General anesthetics, anxiolytics and hypnotics drugs, anti depressants, CNS stimulants and psychotomimetic drugs, Opioid analgesics and opioid anatagonists, Drug dependence and drug abuse, Antiepileptic drugs, Drug therapy for neurodegenerative disorders like parkinson's disease and schizophrenia. |
| **Unit-2: Drugs acting on Autonomic Nervous System (ANS) 7 hours** |
| General introduction, Parasympathomimetic, parasympatholytic, Sympathomimetic, sympatholytic agents, Ganglionic stimulants, blockers and adrenergic neuron blocking drugs, local anesthetics |
| **Unit-3: Drugs acting on Cardiovascular System (CVS) 7 hours** |
| Cardiac glycosides and positive ionotropic agents, Anti-arrhythmic drugs, Antihypertensive drugs, Coronary vasodilators and drugs used in angina, Anti-hyperlipidemic drugs, Fibrinolytic agents, Cardioprotective agents, Anti-anginal agents. |
| **Unit-4: Antihypertensives: 7 hours** |
| Overview, classification of antihypertensive drugs- Diuretics, Sympatholytics, angiotensin inhibitors, vasodilator, dopamine agonists |
| **Unit-5: Drugs acting on Respiratory System and NSAID 7 hours** |
| Expectorants, Anti-tussive bronchodilators, Drugs used in common cold. Classification of NSAIDS, Mechanism of action, NSAIDSwhich do not inhibit prostaglandin synthesis. |
| **Unit-6: Drugs Acting on Blood 5 hours** |
| Agents used to treat anemias and haematopoietic growth factors; Coagulants and anticoagulants; Antiplatelet drugs; Fibrinolytic, antifibrinolytic, plasma expanders |

**Suggested Readings:**

1. Essentials of Medical Pharmacology, K.D Tripathi
2. The Pharmacological Basics of Therapeutics, 5th edition, Goodman and Gillman
3. Basic and Clinical Pharmacology, Bertram G. Katzung

| | |
|---|---|
| Name of The Course | **Pharmacovigilance –I** |
| Course Code | **MSCRT2003** |
| Prerequisite | |
| Corequisite | |

| Antirequisite | | | | |
|---|---|---|---|---|
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**
Students will get exposure about the need and scope of drug safety reporting.

**Course Outcomes**

| | |
|---|---|
| CO1 | Need and scope of Pharmacovigilance, historical aspect of Pharmacovigilance, thalidomide tragedy |
| CO2 | Adverse drug reaction, different classification of ADR, severity and seriousness criteria |
| CO3 | ADR reporting, spontaneous/solicited reporting system, advantages and disadvantages |
| CO4 | Different Pharmacovigilance method, Active and passive surveillance |
| CO5 | Risk benefit assessment of drug, Actual v/s perceived Risk and benefits, Factors affecting benefit risk balance |
| CO6 | Analysis of Drug monitoring |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| Unit-1: Introduction to Pharmacovigilance 7 hours |
| Definitions, Overview and Scope, Importance, History: Pre Thalidomide era, Thalidomide Disaster and Post Thalidomide Era; Pharmacovigilance Current Status and Systems; Pharmacovigilance need and Objectives; Drugs withdrawn from the Market; Vioxx saga. |
| Unit-2: Introduction to adverse drug reaction 7 hours |
| Definitions and classification of ADRs Detection and reporting, Causality assessment, Severity and seriousness assessment, Predictability and preventability assessment, Management of adverse drug reactions |
| Unit-3: Adverse drug reaction reporting 7 hours |
| Introduction to reporting systems; Spontaneous reporting system; Reporting to regulatory authorities; Guidelines for reporting ADRs in biomedical literature. |
| Unit-4: Pharmacovigilance Methods 7 hours |
| Passive Surveillance, Active Surveillance and Stimulated Reporting. PMS Methodologies - Comparative Observational studies, Descriptive Studies, Drug Utilization Studies, Case studies, Cohort studies, Vaccine safety surveillance studies |
| Unit-5: Benefit Risk Assessment 7 hours |
| Actual v/s perceived Risk and benefits, Factors affecting benefit risk balance; Methods of Risk Minimization, Pharmacovigilance Planning. International Expedited reporting ; Pharmacovigilance Planning Guideline |
| Unit-6: Drug monitoring 5 hours |
| WHO Drug monitoring Programme and Uppsala Monitoring centre. Pharmacovigilance Regulations in India and national PV policy and programme. National and international scenario, Pharmacovigilance global perspective |

**Suggested Reading**:
1. Pharmacovigilance for Beginners –Dr. S. Gunasakaran and R.Salhesh Kumar TatamaniMagalirCo-Operative Press, 2010 edition.
2. Textbook of Pharmacovigilance ICRI Institute of Clinical Research (India)
3. Highlights of Pharmacovigilance – P.G Yeolo, DhanalakshmiIyer, 2013 edition.

| Name of The Course | **Drug Discovery and Development Theory (40 Hours)** | | | |
|---|---|---|---|---|
| Course Code | **MSCRT2004** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**
Students will get exposure about the need and scope of clinical research and the areas of clinical research. They will learn about different phases of clinical research.

**Course Outcomes**

| | |
|---|---|
| CO1 | Understand about concepts of Drug Discovery and Development, need for new drug and lead identification |
| CO2 | Understand the concept of pre-clinical evaluation, drug screening type of evaluation |
| CO3 | Clinical safety data management, guidelines on carcinogenicity testing |
| CO4 | Understand about development process of medical device |
| CO5 | Understand about development process of clinical diagnostic, cosmetics and their regulatory aspects |
| CO6 | Analysis of advancement in Drug discovery |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| Unit-1 Evolution of new drugs 7 hours |
| Need for a new Drug, Lead identification, Sources of new drugs and compounds for screening as a potential drug, Drug development process.Drug design-Ligand based, Structure based, Active site identification, |
| Unit-2: Preclinical evaluation –I 7 hours |
| Drug screening, types of evaluation, animal pharmacology, Non clinical overview and non clinicalsummaries(M4S(R2)), Non clinical safety studies(M3(R1)), Guidance on non clinicalsafety studies for the conduct of Human clinical trials and marketing authorization, Dose response information to support drug registration(E4) |
| Unit-3: Preclinical evaluation 2 7 hours |
| Clinical safety data management, guideline on the need of carcinogenicity studies of pharmaceuticals(S1A), Toxicity Studies, Duration of chronic toxicity testing in animals (rodent and non rodent toxicity testing (S4), safety pharmacology studies for human pharmaceuticals (S7A) |
| Unit-4: Medical Device and Vaccines 7 hours |
| Global Regulations for Medical Devices, Classification of medical Devices, Regulatory agencies and regulations, Clinical Trials of Medical Devices; Global Medical Device Nomenclature, Product lifecycle of medical devices. Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device |
| Unit-5: Clinical Diagnostics and Cosmetics 7 hours |
| Objective, scope, definitions, clinical diagnostic, cosmetics and regulatory requirement. Global regulation for cosmetics. |
| Unit-6: Advancement in Drug discovery 5 hours |
| Rational drug discovery, High throughput screening, Structure Activity Relationship (SAR), Quantitative Structure Activity Relationship (QSAR), Computer assisted drug designing (CADD) |

**Suggested Readings**


1. Pharmaceutical Biotechnology by O Kayser, R H Muller
2. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Publisher: Wiley-Blackwell.
3. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., Dupin-Spriet T., Simon P. Publisher: Karger.
4. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)


| Name of The Course | **Global Regulation** | | | |
|---|---|---|---|---|
| Course Code | **MSCRT2005** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:
Students will get exposure about the regulatory requirements of different countries

Course Outcomes

| | |
|---|---|
| CO1 | To know the background of the drug regulation |

| | |
|---|---|
| CO2 | To know the regulatory requirement of US and UK |
| CO3 | To know about the other countries regulation |
| CO4 | To understand the process of IND and NDA |
| CO5 | To know the regulatory requirements for medical device clinical trial |
| CO6 | Analyze the regulation of Biological products |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| Unit-1 : ICH Guideline<br>7 hours |
| Background of drug regulations, International Conference on Harmonization, history of ICH, ICH Structure, ICH Guidelines, Good Clinical Practice- Elements and principle of GCP |
| Unit-2: Regulatory Requirements in US and UK<br>7 hours |
| Food and Drug Act (USFDA), Organization structure and Functions, Code of Federal Regulations related to Clinical Research, EU regulations: EU Clinical Trial Directives, EMEA Structure and Functions, MHRA, Eudralex |
| Unit-3: Other Country Regulations<br>7 hours |
| Regulatory Requirements in China , regulatory system in China , SFDA Structure and Functions, SFDA technical organizations , regulations in China , Regulatory requirements in Japan and Australia, regulatory authorities and laws related to CR, Regulations in other counties related to Clinical Research |
| Unit-4: IND and NDA<br>7 hours |
| IND Application :requirements forms , contents, application , Investigator IND, Treatment IND , Emergency use of IND. NDA application: contents , forms , review process, actions, Guidance documents for IND and NDA, Common Technical Document: Purpose , structure and contents |
| Unit-5: Medical Devices<br>7 hours |
| Global Regulations for Medical Devices, Classification of medical Devices, Regulatory agencies and regulations, Clinical Trials of Medical Devices |
| Unit-6: Biological products<br>5 hours |
| Regulations for Biological products; Types of Biological products. Drug Development for Orphan diseases and Drug legislation. |

**Suggested Readings:**


1. Wong J, Tong R, editors. Handbook of Medical Device Regulatory Affairs in Asia. CRC Press; 2018 Mar 28.
2. Levine RJ. Ethics and regulation of clinical research. Yale University Press; 1988.


## Semester III

| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | **Clinical Trial and Data Management** | | | | |
| Course Code | **MSCRT3001** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

**Course Objectives:**

Students will get exposure about the need and scope of Clinical Data Management in Clinical Research

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Basic concept of Fundamentals of clinical trial design |
| CO2 | Understanding of Planning & strategy of clinical trial design |
| CO3 | Understand the Introduction to Clinical Data Management |
| CO4 | Examine the Database and Query Management |
| CO5 | Demonstrate the Electronic data and lab data loading |
| CO6 | Create the Case report form |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| Unit-1: Fundamentals of clinical trial design 7 hours |
| Objectives of clinical trial design, types of designs- observational, interventional, prospective, retrospective, single and multicentric, randomization, nonrandomization, crossover design, parallel design, comparative design, non-comparative design, single arm, multiple arm, appropriate hypotheses(superiority, inferiority, non-inferiority, equivalency). |
| Unit-2: Planning & strategy of clinical trial design 7 hours |
| Subject's recruitment, recruitment advertisement, and rule for subject withdrawal, eligibility of subject (inclusion and exclusion criteria), study procedure, recruitment period, treatment period, follow-up period, types of control groups including no control, placebo control, and active control, concomitant treatment, various way of randomization, various way of bias, blinding (open label, single blind, double blind, triple blind). |
| Unit-3: Introduction to Clinical Data Management 7 hours |
| Introduction to CDM, Computer system validation (CSV), Clinical Data Management flow, Data Management team, Roles and responsibilities of key team members and sponsor, SOPs of data Management, review and authorization. |
| Unit-4 : Database and Query Management 7 hours |
| Introduction to data base lock, minimum standards, procedure, errors found after database closure, freezing the data base, best practices, recommended Standard Operating Procedures. Introduction to data transfer, procedure, best practices. Role plays of real clinical research stake holders like Clinical research associate, investigator, project manager, volunteer, clinical research coordinator, auditor etc |
| Unit-5: Electronic data and lab data loading 7 hours |
| Electronic data interchange-Architecture for EDI, Advantages of using EDI, barriers to implementation, positives and negatives, Lab data loading -Roles and responsibilities of lab loader technician, helpdesk, study coordinator, -loading lab data, electronic/lab file contents, typical problems, lab data findings, Quality Assurance, SOPs for processing lab data, taking lab data seriously. |
| Unit-6: Case report form 5 hours |
| CRF design , Procedure for CRF design, elements of CRF, data points to be captured in individual CRFs. Database design and build, Introduction to data base design and build, data base design, data base validation. Clinical data entry process, Data entry screen validation, data entry process, symbols, data entering. Guidelines and regulations in Clinical Trial data. |

**Suggested Readings:**


1. Good Clinical Data Management Practices Committee, ICRI.
2. Guide to Clinical Trials (Volume-I &II), DCGI
3. Modules of Clinical trial methodology and management, RHE Life Science (CRO)


| Name of The Course | **Electrophysiology** | | | |
|---|---|---|---|---|
| Course Code | **MSCRT3002** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**

To impart the complete knowledge of Electrophysiology which forms the base of Bioinstrumentation i.e. how Bioelectric signals are generated, propagated, transduced, amplified and recorded. Proper recording of the bioelectric signals help in diagnosis of the diseases.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Understanding of bioelectric phenomena |
| CO2 | Analysing the Interaction of signals |
| CO3 | Examine the Electrical circuit model of the membrane |
| CO4 | Understanding of ECG EMG and EEG |
| CO5 | Analysing of Central nervous system and neuro-control mechanisms |
| CO6 | Analyze the Receptors as Biological Transducers |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| |
|---|
| Unit-1: Introduction to bioelectric phenomena 7 hours |
| Generation, transmission and propagation of signals in nervous systems- Resting Potential, Action Potentials. Synapse, Synaptic Potentials- EPSP (Excitatory Post Synaptic Potentials) and IPSP (Inhibitory Post Synaptic Potentials) Interactions of signals |
| Unit-2: Interaction of signals 7 hours |
| Discussion of initiation and propagation of action potential along nerve fibers. Compound Action Potentials. |
| Unit-3: Electrical circuit model of the membrane 7 hours |
| Electrical circuit models of the Bio-membrane Frequency modulation of the electrical signals. Voltage clamp experiments. |
| Unit-4 : ECG EMG and EEG 7 hours |
| Electrocardiography (ECG) and its diagnostic applications– Generation and propagation of cardiac impulse, SA node as Pacemaker, Ectopic Pacemakers, PQRST Wave Pattern. Various cardiographic leads (Limb leads, Chest leads), Vectorial analysis of normal and diseased heart. Electromyography signals- EMG, its diagnostic applications |
| Unit-5: Central nervous system and neuro-control mechanisms 7 hours |
| Brain Potentials and their generation, recording and diagnostic applications. Neural control mechanism |
| Unit-6: Receptors as Biological Transducers 5 hours |
| Receptors as Biological Transducers, Transduction and Amplification in Receptors; Properties of receptors |

**Suggested Readings:**


4. Introduction to Neurobiophysics, Vasilescu, S.G. Margineanu, Abascus Press, Tunbridge Wells, Vent.
5. Text Book of Medical Physiology, Guyton A.C. and J.E. Hall, Harcourt India Pvt. Ltd.
6. Anatomy and Physiology, Ross and Wilson, Churchill Livingstone.


| Name of The Course | **Operational aspects of clinical research** | | | |
|---|---|---|---|---|
| Course Code | **MSCRT3003** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 4 | 0 | 0 | 4 |

**Course Objectives:**

Students will get exposure about the need and scope of clinical research and the areas of
Clinical research. They will learn about different phases of clinical research.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Operational aspects in CRO and SMO, Site Selection Criteria- Site Selection parameters |
| CO2 | Function of IRB/IEC, responsibility and composition of IRB/IEC |
| CO3 | Roles and responsibility of clinical research players |
| CO4 | Clinical trial documentation, study protocol, CRF, SOPs |
| CO5 | Procedures in clinical trial, Quality Assurance and Quality Control in Clinical Research |
| CO6 | Analysis of QA & QC in clinical research |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| Unit-1: Operation in CRO & SMO 7 hours |
| Site Selection Criteria- Site Selection parameters: Location, Staffing,<br>Qualifications, History, Clinical trial experience, Area of therapeutic experience,<br>Investigational pharmacy, ICH-GCP compliance, Patient enrollment, Site<br>Selection Check list, Site Initiation Visit (SIV) |

| |
|---|
| Single Centre/Multi Centre Trial- Definition, benefits of Single centre and or<br>Multi centre, Differences between Single centre & Multi centre Trial<br><br>Investigator Selection<br>Investigator qualification and agreement, duties delegation, Undertaking by the<br>Investigator, Feasibility study, Other functions-Central lab, Shipment and<br>shipping records, meetings with Sponsor, analysis & interpretation of results etc<br><br>Operation of Institutional Review Board (IRB)/ Independent Ethics Committee<br>(IEC) - Defining Scope of IRB/IEC Authority, Responsibilities of IRB/IEC, Composition<br>of IRB/IEC, Basic Functions, Operation and Procedure of IRB/IEC, Communication with<br>IRB, IRB/IEC Records, Documents for submission to IRB/IEC, Difference between IRB and IEC |
| Unit-2: Operation of IRB/IEC 7 hours |
| Defining Scope of IRB/IEC Authority, Responsibilities of IRB/IEC, Composition<br>of IRB/IEC, Basic Functions, Operation and Procedure of IRB/IEC, Communication with<br>IRB, IRB/IEC Records, Documents for submission to IRB/IEC, Difference between IRB and IEC |
| Unit-3: Roles & Responsibilities of Clinical Trial Personnel 7 hours |
| Roles & Responsibilities of Sponsor, Investigator, CRO/SMO, CRA/Monitor, Auditor, Clinical Research co-coordinator, Clinical Data Manager, Clinical Biostatistician |
| Unit-4 : Clinical Trial Documentation 7 hours |
| Investigator's Brochure- Confidentiality Statement, Summary, Introduction, structure and content<br>Study Protocol – Structure and content<br>Case Report Forms (CRF) & e-CRF-Structure and content<br>Informed Consent Form/Assent Form- structure and content<br>Clinical Study Report-structure and content<br>Standard Operating Procedures (SOP) in Clinical Trials-Need of SOPs, What is<br>SOPs, Benefits of SOPs, different types of SOPs, SOP Writing SOPs and Guideline, |
| Implementation and monitoring of SOPs, Change control.<br>Essential Documents-Importance of Essential Documents, Pre-study/during and post study documents |
| Unit-5: Procedures in Clinical Trial 7 hours |
| Interventions, Study Drug Packaging and Distribution of Study Drug Receipt,<br>Dispensing, Accountability, Storage, Disposal, Regulatory Requirement.<br><br>Monitoring in Clinical Trials: Purpose of monitoring & Monitor's<br>responsibilities, Monitoring procedures, Monitoring report, Audit, Extent and nature of monitoring, Medical Monitoring, Query Resolution |
| Unit- 6: QA & QC 5 hours |
| Quality Assurance and Quality Control in Clinical Research –Introduction, Regulatory requirement of quality Assurance (QA) and Quality Control (QC) in Clinical Research, Role and Responsibilities of QA personnel, Different types of Audit, Quality System and Quality Policy, Continual Process Improvement |

**Suggested Readings:**

1. Guide to Clinical Trials,Bert Spilker, 1991 (Now 3rd edition).
2. Ethical guidelines for Biomedical Research on Human Subject, ICRI Government Published 2000
3. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ
4. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)

| **Name of The Course** | **Clinical trial amended rule** | | | |
|---|---|---|---|---|
| **Course Code** | **MSCRT3004** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Objectives:**

The basic objective of this course is to get familiar with new drug clinical trial rule 2019.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Introduction to CDSCO structure and organogram |
| CO2 | Chapter 1 to Chapter 6 of NDCT 2019 |
| CO3 | Chapter 7 to Chapter 13 of NDCT 2019 |
| CO4 | Rule 1 to rule 107 of NDCT 2019 |
| CO5 | Schedule 1 to schedule 8 of NDCT 2019 |
| CO6 | Form 1 to form 27 of NDCT 2019 |

**Course Content**

| |
|---|
| Unit-1: CDSCO Structure and Organogram<br>7 hours |
| Central licensing authority (CLA), State licensing Authority (SLA), Schedule 1 and Schedule 2 |
| Unit-2: Chapter Part-I<br>7 hours |
| Chapter 1 to chapter 6 |
| Unit-3: Chapter Part-II<br>7 hours |
| Chapter 7 to chapter 13 |
| Unit-4: Rules (NDCT 2019)<br>7 hours |
| Rules 1 to rules 107 |
| Unit-5 : Schedules (NDCT 2019)<br>7 hours |
| Schedule 1 to schedule 8 |
| Unit-6: Forms (NDCT 2019)<br>5 hours |
| Form 1 to form 27 |

**Suggested Readings:**

NDCT 2019 (https://cdsco.gov.in/opencms/opencms/Pdf-documents/NewDrugs_CTRules_2019.pdf)

| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | **Clinical project and dissertation** | | | | |
| Course Code | **MSCRP4051** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 0 | 0 | 28 | 14 | |

**Course Objectives:**

Students will get exposure of Project work execution in the area of Clinical Research.

**Course Outcomes**

**On completion of this course the students will be able to**

| | |
|---|---|
| CO1 | Formulate questions and to discover feasible solutions |
| CO2 | Demonstrate individual initiative or group responsibility |
| CO3 | Use resource materials to express ideas and talents |
| CO4 | Design and execute the project work |
| CO5 | Report the project work in terms of thesis |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **60** | **00** | **240** | **300** |

**Course Content**

| |
|---|
| Unit-1: Clinical trial Project<br>9 hours |
| Six components are required for project completion: 1.Self-Management component<br>3. Written component 3. Research component 4. Oral component 5. Technological component 6. Visual component<br><br>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. Students will also be exposed to ongoing clinical research activities viz., different Phases of CTs, bioavailability (BE) and bioequivalence (BE) studies, pharmacokinetics, pharmacodynamics, monitoring and audit of CTs, data management, drug regulatory activities and statistical software used in clinical research |

GALGOTIAS UNIVERSITY

(Established under Galgotias University Uttar Pradesh Act No. 14 of 2011)

# Program: B.Sc. Medical Biotechnology

**Scheme: 2020-2021**

**Vision:** To be known globally for education, innovation and interdisciplinary research in Biosciences, Healthcare and Biomedical Engineering.

**Mission:**

**M1**. To establish the centre of excellence in medical biotechnology.

**M2**. To establish state-of-the-art facilities of medical biotechnology for world class education and research.

**M3**. To conduct the multidisciplinary research in collaboration with national and international organization for developing the innovative solutions of unsolved health problems.

**M4**. To develop medical biotech leaders having regulatory and ethical mindset with capability of creating value in healthcare organization.

**Program Educational Objectives:**

**PEO** 1. Graduates shall conduct the research in biotechnology, healthcare, biomedical science and interdisciplinary field efficiently and ethically.

**PEO** 2. Graduates of medical biotechnology shall excel in higher studies and interdisciplinary research exhibiting global competitiveness.

**PEO** 3. Graduates have a high sense of medical responsibilities and ethical thinking and solve new/unsolved/unmet medical need

**Program Specific Objectives:**

**PSO**1. Evaluate critical domestic and global regulatory and health care issues that challenge and influence biomedical and biotech product development

**PSO**2. Demonstrate competencies in performing the biotech research; evaluating, analysing and presenting the biotech research results.

**PSO**3. Effectively communicate and collaborate with biotech service providers and regulatory agencies to develop culturally diverse domestic and global strategies for medical biotechnology.

**PSO**4. Demonstrate regulations, social and ethical values required to make a global biotech research professional

**Program Outcomes:**

**PO1- Medical Biotechnology Knowledge**: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of Medical Biotechnology, including Human Physiology, Bioinstrumentation, Biosafety, Pharmacology and Toxicology, Microbial Technology, Drug Development, Genetic Engineering, Immunotechnology, Medicinal chemistry, Animal Biotechnology, Biomaterials & Tissue Engineering, Industrial Bioprocess Technology, and Molecular Diagnostics & Therapeutics.

**PO2- Planning Abilities**: Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

**PO3- Problem analysis**: Utilize the principles of Analytical thinking, clearly and critically, while solving problems and making decisions during research design. Find, analyse, evaluate and apply information systematically and making decisions related to Medical Biotechnology.

**PO4- Modern tool usage**: Learn and apply modern and appropriate tools related to Medical Biotechnology. As example, Drug Designing, Statistical Analytical System (SAS), Molecular Diagnostics & Therapeutics, Immunotechnology, and Industrial Bioprocess Technology.

**PO5- Leadership skills**: Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfilment of practice, professional and societal responsibilities.

**PO6- Professional Identity**: Understand, analyse and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, Medical Biotechnologist, managers, employers, employees)

**PO7- Medical Biotechnology Ethics**: Honour human values and apply ethical principles in research, professional and social contexts. Demonstrate behaviour that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions during the conduction of studies related to Medical Biotechnology.

**PO8- Communication**: Communicate effectively with the Medical & Healthcare community.

**PO9- The Medical Biotechnology and society**: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the Medical Biotechnology practices.

**PO10- Environment and sustainability**: Understand the impact of the Medical Biotechnology solution in societal and environmental contexts, demonstrate the knowledge of, and need for Bio Waste Management.

**PO11- Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-access and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

## Curriculum

| Semester 1 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sl. No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BMBT1001 | Biomolecules and Metabolism | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMBT1002 | Cell and Molecular Biology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BMBT1003 | Human Physiology- I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BMBP1051 | Medical Biotechnology Lab-I | 0 | 0 | **2** | 1 | 50 | -- | 50 |
| 5 | | Disruptive technologies | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 6 | | Professional communication | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 7 | | Environmental Studies | 0 | 0 | **1** | 0.5 | 50 | -- | 50 |
| 8 | | Campus to corporate | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 9 | | Ethics and Professional Competency | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 10 | | Creative / Liberal Arts | 0 | 0 | **1** | 0.5 | 50 | -- | 50 |
| 11 | | Waste management | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 12 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **20** | **0** | **4** | **22** | **330** | **270** | **600** |
| **Semester II** | | | | | | | | | |
| Sl No | Course Codee | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BMBT2001 | Bioinstrumentation-I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMBT2002 | Human Physiology -II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BMBT2003 | Research Methodology & Biostatistics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BMBT2004 | Microbial Technology | 4 | 0 | 0 | 4 | 20 | 30 | 50 |
| 5 | BMBP2051 | Medical Biotechnology Lab -II | 0 | 0 | **2** | 1 | 50 | -- | 50 |
| 6 | | Professional communication | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 7 | | Foreign Language | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 8 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **19** | **0** | **2** | **20** | **190** | **210** | **400** |
| **Semester III** | | | | | | | | | |
| Sl No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BMBT3001 | Genetic Engineering | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMBT3002 | Immunotechnology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BMBT3003 | Bioinstrumentation - II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BMBT3004 | Pharmacology and Toxicology | 4 | 0 | 0 | 4 | 20 | 30 | 50 |
| 5 | BMBP3051 | Medical Biotechnology Lab -III | 0 | 0 | **2** | 1 | 50 | -- | 50 |
| 6 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 7 | | Disaster Management | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 8 | | AI and its application | 0 | 0 | **4** | 2 | 50 | -- | 50 |
| 9 | | Creativity, Innovation and entreperneurship and IPR | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **17** | **0** | **6** | **20** | **240** | **210** | **450** |
| **Semester IV** | | | | | | | | | |
| Sl No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BMBT4001 | Medical Microbiology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMBT4002 | Fundamentals of Bioinformatics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 3 | BMBT4003 | Animal Biotechnology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BMBT4004 | Fundamentals of Clinical Research | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | BMBT4005 | Drug Discovery and Development | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | | **Electives (Group I)** | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 7 | BMBP4051 | Medical Biotechnology Lab -IV | 0 | 0 | **2** | 1 | 50 | -- | 50 |
| 8 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **19** | **0** | **2** | **20** | **190** | **210** | **400** |
| **Semester V** | | | | | | | | | |
| **Sl No** | **Course Code** | **Name of the Course** | | | | | **Assessment Pattern** | | |
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| 1 | BMBT5001 | Biomaterials & Tissue Engineering | 4 | 0 | 0 | 4 | 20 | 30 | 50 |
| 2 | BMBT5002 | Nanobiotechnology and Biosensors | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BMBT5003 | Industrial Bioprocess Technology | 4 | 0 | 0 | 4 | 20 | 30 | 50 |
| 4 | BMBT5004 | Regulatory affairs and Ethics in Clinical Research | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | BMBT5005 | Molecular Diagnostics & Therapeutics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | | **Electives (Group II)** | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 7 | BMBP5051 | Medical Biotechnology Lab -V | 0 | 0 | **2** | 1 | 50 | -- | 50 |
| | | **Total** | **20** | **0** | **2** | **21** | **170** | **180** | **350** |
| **Semester VI** | | | | | | | | | |
| **Sl No** | **Course Code** | **Name of the Course** | | | | | **Assessment Pattern** | | |
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| **1** | BMBP5051 | Project Work | 0 | 0 | 34 | 17 | 60 | -- | 240 |
| | | **Total** | **0** | **0** | **34** | **17** | 60 | -- | 240 |

**List of Electives**

**Elective-I**

| **Sl No** | **Course Code** | **Name of the Electives** | | | | | **Assessment Pattern** | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| 1 | BMBT4006 | Introduction to Healthcare | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMBT4007 | Evolutionary Biology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BMBT4008 | Designing Clinical Trials | 3 | 0 | 0 | 3 | 20 | 30 | 50 |

**Elective-II**

| **Sl No** | **Course Code** | **Name of the Elective** | | | | | **Assessment Pattern** | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| 1 | BMBT5006 | Medical writing | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMBT5007 | Genomics & Proteomics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BMBT5008 | Electrophysiology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |

# Semester I

| **Name of The Course** | **Biomolecules and Metabolism** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT1001** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives**:
Students will understand about biochemical reactions, structure, function and metabolism of carbohydrate, lipids, proteins and nucleic acid.

**Course Outcomes**:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the basic concepts of chemical basis of life |
| CO2 | Understand the structure, function and metabolism of carbohydrates |
| CO3 | Understand the structure, function and metabolism of lipids |
| CO4 | Understand the structure, function and metabolism of proteins |
| CO5 | Understand about the structure, function and metabolism of nucleic acids. |
| CO6 | Analyze the Metabolism of macromolecules |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content:**

| **Unit-1: Introduction** | 6 hours |
|---|---|
| Chemical basis of life; Composition of living matter; Water – properties, pH, ionization and hydrophobicity; Emergent properties of biomolecules in water; Biomolecular hierarchy; Macromolecules; Molecular assemblies; Structure-function relationships; Acid base balance and their importance in clinical biochemistry. Bioenergetics-basic principles; Equilibria and concept of free energy; Coupled processes | |

| **Unit-2: Carbohydrate** | 6 hours |
|---|---|
| Carbohydrates: Classification, structure, occurrence and biological functions. Physicochemical properties of monosaccharides, oligosaccharides. Glycoproteins and proteoglycans. | |
| **Unit-3: Lipids** | 6 hours |
| Lipid: Classification, structure, occurrence and biological functions of lipids. Nomenclature and properties of fatty acids and triglycerides. Biosynthesis of saturated and unsaturated fatty acids. Biosynthesis of triglycerides, phospholipids, Sphingolipids, cholesterol and prostaglandins. | |
| **Unit-4: Proteins** | 6 hours |
| Amino acids: Physicochemical and structural properties of amino acids, Titration curve, isoelectric point. Proteins: Classification, structure, peptide bond, Conformation of proteins (Ramachandran plot, secondary, tertiary and quaternary structure; domains; motif and folds. Properties and biological functions of proteins. Amino acid sequencing techniques. | |
| **Unit-5: Nucleic acids** | 6 hours |
| Nucleic acids: properties of DNA in solution, Composition of RNA and DNA, generalized structure plan of nucleic acids, features of A, B, H and Z DNA, Structure and roles of different types of DNAs and RNAs Nucleic acid Metabolism: Sources of atoms in purine and pyrimidine molecules, biosynthesis and degradation of purines and pyrimidines, regulation of purine and pyrimidine biosynthesis, structure and regulation of ribonucleotide reductase. Biosynthesis of ribonucleotides, deoxyribonucleotides and polynucleotides. Inhibitors of nucleic acid biosynthesis. | |
| **Unit-6: Metabolism of macromolecules 10 hours** | |
| **Carbohydrate Metabolism**: Reactions and energetics of glycolysis. Alcoholic and lactic fermentations, Reactions and energetics of TCA cycle, gluconeogenesis, glycogenesis and glycogenolysis. Reactions and physiological significance of HMP pathway. **Lipid metabolism**: Transport and mobilization of lipids, oxidation of saturated fatty acids (α-, β- , ω), | |

| |
|---|
| oxidation of unsaturated and odd-chain fatty acids, role of carnitine intransport of fatty acid, energetics of β-oxidation scheme, metabolism of ketone bodies and its biological significance. **Amino acid metabolism**: General reactions of amino acid metabolism- Transamination, Deamination and Oxidative decarboxylation. Biosynthesis and degradation of amino acids and their regulation. Urea cycle and its regulation; **Nucleic acid metabolism**: Porphyrin Metabolism: Biosynthesis and degradation of porphyrins. |

**Suggested Readings**


1. V.Voet and J.G.Voet, Biochemistry, 3rd edition, John Wiley, New York, 2004.
2. A.L. Lehninger, Principles of Biochemistry, 4th edition, W.H Freeman and Company, 2004.
3. L. Stryer, Biochemistry, 5th edition, W.H. Freeman and Company, 2002.
4. Biochemical calculations (1976) by Irwin H. Seghal (John Wiley and Sons Inc.).
5. Biochemistry (2004) by Voet Donald Voet, Judith G. (J Wiley and Sons.).
6. Physical biochemistry (1982) by D. Freifilder (W.H. Freeman and Company).


| **Name of The Course** | **Cell and Molecular Biology** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT1002** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**
Students will understand about the structure and functions of cells and central dogma.

**Course Outcomes:**
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the basic concepts cell cycle and cell signalling |
| CO2 | Understand the Membrane Structure and Function. |
| CO3 | Understand the DNA Replication and repair mechanisms |
| CO4 | Understand the transcription and Post transcriptional modifications |
| CO5 | Understand about the translation and post translational modifications. |
| CO6 | Analyze the Mutation & DNA Repair mechanism |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Introduction** | **7 hours** |
|---|---|
| Cell organelles- Mitochondria, ribosomes, Golgi bodies, Endoplasmic reticulum; nucleus; Cell division and cell cycle: Mitosis and meiosis, steps in cell cycle, and control of cell cycle. Cell signaling: Hormones and their receptors, second messengers, signalling through G protein coupled receptors. | |
| **Unit-2: Membrane Structure and Function** | **7 hours** |
| Structural models; Composition and dynamics; Transport of ions and macromolecules; Pumps, carriers and channels; Endo- and Exocytosis; Membrane carbohydrates and their significance in cellular recognition; Cellular junctions and adhesions; Structure and functional significance of plasmodesmata. | |
| **Unit-3: DNA Replication** | **7 hours** |
| Prokaryotic and Eukaryotic replication: models for replication, Unit of replication, replication initiation, elongation and termination, replication inhibitors. | |
| **Unit-4: Transcription and Post transcriptional modifications** | **7 hours** |
| Prokaryotic and Eukaryotic transcription: RNA polymerases, General and specific transcription factors, Promoters, insulator, repressor, enhancer, modifications in RNA: Cap formation, polyadenylation, Splicing and RNA Editing; Gene regulation in Bacteria, Gene silencing, Overview of ribozyme technology | |
| **Unit-5: Translation** | **7 hours** |
| Prokaryotic and eukaryotic translation: Translation machinery, initiation, elongation and termination, factors, translational inhibitors, post translational modifications | |
| **Unit-6: Mutation & DNA Repair 5 hours** | |

| |
|---|
| Mutation: Types and causes, mutant types – lethal, conditional, biochemical, loss of function, gain of function DNA Repair: Direct reversal, Excision repair -nucleotide and base excision, Mismatch repair Translesion DNA synthesis, Recombination repair, SOS Response |

**Suggested Readings**


1. Cell and molecular biology-Concept and experiment. 2nd edn., Harris,D(Ed.), Karp, G.1999. John wiley & sons, sons, New York.
2. Lodish et al., Molecular cell Biology, 4th Edition, W.H. Freeman & Company, 2000.
3. Smith & Wood, Cell Biology, 2nd Edition, Chapman & Hall, London, 1996.
4. Watson et al., Molecular Biology of the gene, 5th Edition, Pearson Prentice Hall. USA, 2003.
5. B. M. Turner, Chromatin & Gene regulation, 1st Edition, Wiley-Blackwell, 2002.
6. Benjamin Lewin, Gene IX, 9th Edition, Jones and Barlett Publishers, 2007.
7. A.L. Lehninger, Principles of Biochemistry, 4th edition, W.H Freeman and Company, 2004.
8. L. Stryer, Biochemistry, 5th edition, W.H. Freeman and Company, 2002.


| **Name of The Course** | **Human Physiology-I** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT1003** | | | |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50 % marks in aggregate | | | |
| Corequisite | Basic knowledge of physiology. | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**: Students are able to understand the basic concept of Physiology and they can apply the knowledge of physiology in understanding the various diseases and keeping the body in healthy state.

**Course Outcomes**

| | |
|---|---|
| CO1 | Understand the Digestive system. |
| CO2 | Interpret the composition of blood and its function circulatory system of human |
| CO3 | Interpret the circulatory system in human |
| CO4 | Evaluate the respiratory system |
| CO5 | Understand the excretory system. |
| CO6 | Analyze the Male Reproductive system |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1 Digestive system** | **7 Hours** |
|---|---|
| Digestive system – Homeostasis, structure of stomach and intestine, Digestive gland and Hormones, Digestion of food in different parts of alimentary canal, absorption and assimilation. | |
| **Unit-2 Blood and circulation** | **7 Hours** |
| Blood and circulation - Blood corpuscles, hemopoieses and formed elements, plasma function, blood volume, WBC and platelets function. Anemia, thalassemia, Leukemia, Polycythemia, Hemostasis and blood coagulation mechanism, blood groups and blood banking. hematocrits value | |
| **Unit-3 Cardiovascular System** | **7 Hours** |
| Cardiovascular System: Comparative anatomy of heart structure, myogenic heart, specialized tissue, ECG – its principle and significance, cardiac cycle, heart as a pump, blood pressure, neural and chemical regulation. | |
| **Unit-4 Respiratory system** | **7 Hours** |
| Respiratory system – structure of lungs and surfactant function, Mechanism of breathing, anatomical considerations, alveolar ventilation, vital capacity of lungs, transport of gases, exchange of gases, waste elimination, neural and chemical regulation of respiration. | |
| **Unit-5 Excretory system** | **7 Hours** |
| Excretory system - Comparative physiology of excretion, kidney, urine formation, urine concentration, waste elimination, micturition, | |

| |
|---|
| regulation of water balance, blood volume, blood pressure, electrolyte balance, acid-base balance. |
| **Unit-6: Male Reproductive system 5 Hours** |
| Testis, Duct system, Functions. Semen-secretion, composition, Oligozoospermia. |

**Suggested Readings**


4. Guyton A.C, Hall J.E, Textbook of Medical Physiology, 11th Ed., Saunders Company, 2005.
5. Widmaier E. P, Raff H, Strang K. T. Vander's, Human Physiology : The mechanism of Body Function, 9th Ed. Mc. Graw Hill, 2003.
6. Ganong W. E, Review of Medical Physiology, 21st Ed., Mc. Graw Hill, 2003.


# Semester II

| **Name of The Course** | **Bioinstrumentation-I** | | | | |
|---|---|---|---|---|---|
| **Course Code** | **BMBT2001** | | | | |
| Prerequisite | Candidate for admission to the first year of B.Sc. Degree Course in Biochemistry should passed the Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology with a minimum of 50 % marks in aggregate. | | | | |
| Corequisite | Students should have the basic knowledge of chemistry and environmental science. | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

**Course Objectives**: Students are able to understand the basic concept of Spectroscopy Techniques, microscopy, Chromatography Techniques and Electrophoretic techniques.

**Course Outcomes**

| | |
|---|---|
| CO1 | Describe Different methods of protein precipitation, Lyophilization; Buffers; Methods of cell disintegration |
| CO2 | Explain various Spectroscopy Techniques |
| CO3 | Describe the Basic principles and applications of microscopy |
| CO4 | Explains Chromatography Techniques. |
| CO5 | Explain basic concepts of Electrophoretic techniques |
| CO6 | Analyze various Filtration techniques |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Basic Techniques 7 hours** |
|---|
| Different methods of protein precipitation: Precipitation using inorganic salts (salting out) and organic solvents, isoelectric precipitation, Lyophilization; Buffers; Methods of cell disintegration; Enzyme assays and controls; Detergents and membrane proteins |
| **Unit-2 Spectroscopy Techniques 7 hours)** |
| UV, Visible and Raman Spectroscopy; Theory and application of Circular Dichroism; Fluorescence; MS, NMR, PMR, ESR and Plasma Emission spectroscopy, FTIR |
| **Unit-3 MICROSCOPY 7 hours** |
| Basic principles and applications of - Light microscopy, Bright & Dark Field microscopy, Fluorescence microscopy, Phase Contrast microscopy, TEM, SEM, Confocal Laser microscopy, Radio Microscopy. |
| **Unit-4 Chromatography Techniques 7 hours** |
| TLC and Paper chromatography; Chromatographic methods for macromolecule separation - Gel permeation, Ion exchange, Hydrophobic, Reverse-phase and Affinity chromatography; HPLC and FPLC; Criteria of protein purity |
| **Unit-5 Electrophoretic techniques 7 hours** |
| Theory and application of Polyacrylamide and Agarose gel electrophoresis; Capillary electrophoresis; 2D Electrophoresis; Disc gel electrophoresis; Gradient electrophoresis; Pulsed field gel electrophoresis |
| **Unit-6: Filtration techniques 5 hours** |

| |
|---|
| Gravity Filtration, Vacuum (or Suction) Filtration, Dialysis, Ultrafiltration and other membrane techniques |

**Suggested Readings**:


1. Principles and Techniques of Practical Biochemistry Wilson, K., Walker, J. (eds.); Cambridge University Press, Cambridge, 2000, 784 pp., ISBN 0-521-65873.
2. An Introduction to Practical Biochemistry (1998) 3rd ed., Plummer D. T., Tata McGraw Hill Education Pvt. Ltd. (New Delhi), ISBN:13: 978-0-07-099487-4 / ISBN:10: 0-07-099487-0.
3. Physical Biochemistry: Principles and Applications (2010) 2nd ed., Sheehan, D., Wiley Blackwell (West Sussex), ISBN:978-0-470-85602-4 / ISBN:978-0-470-85603-1.
4. Physical Biochemistry: Applications to Biochemistry and Molecular Biology (1982) 2nd ed., Freifelder, D., W.H. Freeman and Company (New York), ISBN:0-7167-1315-2 / ISBN:0-7167-1444-2.


| **Name of The** | **HUMAN PHYSIOLOGY-II** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT2002** | | | |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50 % marks in aggregate. | | | |
| Corequisite | Basic knowledge of human physiology | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**: Students are able to understand the basic concept of Physiology and they can apply the knowledge of physiology in understanding the various diseases and keeping the body in healthy state.

**Course Outcomes**

Students are able to

| | |
|---|---|
| CO1 | Describe Structure of Neurons, action potential, Neurotransmitter |
| CO2 | Explain Mechanism of Muscle contraction in skeletal tissue |
| CO3 | Describe Structure and functional anatomy of eye and ear |
| CO4 | Explains Endocrinology including hormones and their action |
| CO5 | Explain Reproductive processes |
| CO6 | Understand the Skeletal physiology |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1 Nervous system 7 hours** |
|---|
| Nervous system: Structure of Neurons, action potential, Neurotransmitter, gross neuroanatomy of the brain and spinal cord, central and peripheral nervous system, Structure of cerebrum and function of different area of cerebral cortex, memory and cognition, Thermoregulation, mechanism of thermo sensation pathways. |
| **Unit-2 Muscle physiology 7 hours** |
| Muscle physiology: Mechanism of Muscle contraction in skeletal tissue, structural and function difference between skeletal muscle and cardiac muscle. Structure of actin and myosin filament, Tetany, muscular dystrophy. |
| **Unit-3 Sensory system 7 hours** |
| Sensory system: Functional anatomy of eye, Structure and functional anatomy of retina, Structure of rod and cone cells and their pigments, Molecular mechanism of rhodopsin, mechanism of Vision, hyperpolarization of rod receptor potential, Functional anatomy of ear; structure and function of organ of corti, Inner hair cells (IHC) and outer hair cells (OHC) stereocilia, mechanism of Hearing. Common disorders of the following sensations: Vision, Hearing, Taste, Smell and Touch |
| **Unit-4 Endocrine System 7 hours** |
| Endocrinology: Endocrine glands: Pituitary gland and hormone, thyroid gland and its hormone, adrenal gland and its hormone function, basic mechanism of hormone action, hormones and diseases. |

| **Unit-5 Female Reproductive system 7 hours** |
|---|
| Reproductive system: Reproductive processes, gametogenesis, ovulation, neuroendocrine regulation, Menstrual cycle, Hormones related to ovulation and reproductive cycle. |
| **Unit-6 Skeletal physiology 5 hours** |
| Cartilage – types with example & histology, Bone – Classification, names of bone cells, parts of long bone, microscopy of compact bone, names of bones, vertebral column, fontanelles of fetal skull, Joints – Classification with examples |

**Suggested Readings:**


4. Guyton A.C, Hall J.E, Textbook of Medical Physiology, 11th Ed., Saunders Company, 2005.
5. Widmaier E. P, Raff H, Strang K. T. Vander's, Human Physiology : The mechanism of Body Function, 9th Ed. Mc. Graw Hill, 2003.
6. Ganong W. E, Review of Medical Physiology, 21st Ed., Mc. Graw Hill, 2003.


| **Name of The Course** | **Research Methodology & Biostatistics** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT2003** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 4 | 0 | 0 | 4 |

**Course Objectives:**

Students will get exposure about Research Methodology

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Research |
| CO2 | Understand about the Research Design |
| CO3 | Understand about the Research Report and ethics |
| CO4 | Understand about the Sampling methods |
| CO5 | Understand about the Measures of central tendency |
| CO6 | Understand about Hypothesis testing |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Introduction to Research** | **8 hours** |
|---|---|
| Research definition, types, advantage and significance. Introduction to research methods, identifying research problem, definition, objectives, role, scope in biotech research, process of research, limitations & types | |
| **Unit-2: Research Design** | **7 hours** |
| Concept of Interdisciplinary Research, Procedures in research. Types of Research Design: Experimental/Interventional research, Quasi-experimental studies, Observational research. Sources of Experimental Errors. Survey research: Types of surveys- CATI, CAPI, Mail, Email, Face-to-face, Questionnaire | |
| **Unit-3: Research Report and ethics** | **5 hours** |
| Type of research report- Research, review, case report, manuscript, monograph, book chapters. Structure of Research Reports. Quoting of reference and bibliography using reference management tools. Ethical issues in research, plagiarism. | |
| **Unit-4: Sampling methods** | **5 hours** |
| Sampling methods, Advantages and Limitation, Sampling process, Types of Sampling, Probability and Non Probability sampling techniques, sampling errors, Data collection Primary and secondary data, Collection and validation. | |
| **Unit-5: Measures of central tendency** | **8 hours** |
| Measures of central tendency- Mean, Median, Mode; Measures of dispersion- Range, Mean deviation and Coefficient of variation, Standard deviation, Standard error; Correlation and regression; Statistical inference- Hypothesis testing, Significance level, Confidence interval, t-test, z-test. Test of significance for large and small samples; Parametric tests; Non parametric tests; Experimental design, Use of biostatistic softwares. | |
| **Unit-6: Hypothesis testing** | **7 hours** |
| Null hypothesis and test of significance (t-test, paired t-test, Analysis of variance, Analysis of covariance, Coefficient of Variation, chi-square | |

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|---|
| test, Fischer exact, Mann-Whitney, Wilcoxin, McNeman test, Kruskal Wallis. |

**Suggested Readings**:


9. Graziano AM, Raulin ML. Research methods: A process of inquiry. HarperCollins College Publishers; 1993.
10. C.R. Kothari : Research Methodology, New Age International Publishers
11. Bouma GD, Ling R, Wilkinson L. The research process. Oxford: Oxford University Press; 1993 Mar 30.
12. Dawson B, Trapp RG. Basic and clinical biostatistics. Singapore. 2004;2001:141-2.


| **Name of The Course** | **Microbial Technology** | | | | |
|---|---|---|---|---|---|
| **Course Code** | **BMBT2004** | | | | |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50 % marks in aggregate | | | | |
| Corequisite | Basic knowledge of microbiology | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

**Course Objectives**: Students are able to understand about Bacterial Growth, Microbial strain improvement, Production of microbial enzymes and its applications and Microbial Fuel Cell.

**Course Outcomes**

| | |
|---|---|
| CO1 | Explain the basic concepts of History and scope of microbial biotechnology |
| CO2 | Analyze the Bacterial Growth curve |
| CO3 | Understand the Bacterial Metabolism |
| CO4 | Illustrate the basic concept of Microbial strain improvement |
| CO5 | Interpret the Production of microbial enzymes and its applications |
| CO6 | Discuss the Microbial Fuel Cell. |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **UNIT I History and scope of microbial biotechnology** | **7 hours** |
|---|---|
| History and scope of microbial biotechnology, Microbial biodiversity and its use, basic functions of CBD. Berge's manual of systemic bacteriology. Mass cultivation and preservation of microorganisms. Mycotechnology, Classification in microbial biomass | |
| **Unit-2 Bacterial Growth** | **5 hours** |
| Bacterial Growth- Growth curve, measuring the bacterial growth, factors effecting bacteria growth-physical and nutritional factors. Prevention of bacterial growth- Physical and chemical control of organisms, different mode of antibiotic action. | |
| **Unit-3 Bacterial Metabolism 7 hours** | |
| Metabolism-Glycolytic pathway, alternative of glycolytic pathway, Fermentation, Kerb's cycle and electron transport and oxidative phosphorylation. Other metabolic pathway- Photoautotrophy, Photoheterotrophy and Chemoautotrophy. Microbes in extreme environment – Adaptation mechanism of Halophiles, alkaliphiles, psychrophiles, Piezophile and xerophile | |
| **Unit-4 Microbial strain improvement** | **7 hours** |
| Microbial strain improvement -Screening and isolation of microorganisms, primary and secondary metabolites, enrichment, specific screening for desired product. Modern trends in microbial production-Modern trends in microbial production of bioplastics (PHB, PHA), bioinsectides, biopolymer (dextran, alginate, xanthan). Biofuels Microbial production of hydrogen gas, biodiesel from. Fungal enzymes of commercial importance and production of mammalian proteins from fungi. Case studies can be provided depending on any recent issue. | |
| **Unit-5 Production of microbial enzymes and its applications** | **7 hours** |
| Production of microbial enzymes and its applications, microbial production of antibiotics. Bioremediation of Xenobiotic and natural | |

| |
|---|
| compounds - microbes in mining, ore leaching, MEOR, waste - water treatment, biodegradation of non cellulose and cellulosic wastes for environmental conservation. Lignocellulosic waste degradation. Treatment of urban (sewage) and industrial effluents. Biomass from carbohydrates. |
| **Unit-6 Microbial Fuel Cell** **7 hours** |
| Microbial Fuel Cell: Types of Biological fuel cells – Working Principle - Applications of biological Fuel cells. A brief study of the principle, construction of different types of fuel cells. Hydrogen production by photosynthetic bacteria, biophotolysis of water and by fermentation; Microbial recovery of petroleum by biopolymers (Xanthum gum), biosurfactants |

**Suggested Readings:**


1. Michael J. Pelezar, J.R.E.C.S Chan, Noel R. Erieg,(2005), Microbiology (5th Ed) TATA McGraw Hill
2. Anantha Narayan, C.K. Jayaram Paniker, (2009), Text Book of Microbiology (7 th Ed) Orient Blackswan
3. Presscott and Dunn,(2006) Industrial Microbiology" CBS Publishers
4. B.H.Khan,(2006) Non-conventional Energy Sources , The McGraw Hill Companies


# Semester III

| **Name of The Course** | **Genetic Engineering** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT3001** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:
Students will get exposure about the tools and techniques of genetic engineering.

**Course Outcomes:**
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of genetic engineering |
| CO2 | Understand about the Cloning Vectors |
| CO3 | Understand about the Cloning Methodologies |
| CO4 | Understand about the concepts of PCR and Its Applications |
| CO5 | Understand about the Sequencing methods and other techniques |
| CO6 | Analyze the Genetic engineering techniques |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| |
|---|
| **Unit-1: Basics Concepts** **7 hours** |
| DNA manipulation enzymes; Cohesive and blunt end ligation; Linkers; Adaptors; Homopolymeric tailing; Labeling of DNA: Nick translation, Random priming, Radioactive and non-radioactive probes, Hybridization techniques: Chromatin Immunoprecipitation; DNA-Protein Interactions |
| **Unit-2: Cloning Vectors** **7 hours** |
| Cloning vectors, Phagemids; Lambda vectors; Insertion and Replacement vectors; Cosmids; Artificial chromosome vectors; Animal Virus derived vectors-SV-40; vaccinia/bacculo & retroviral vectors; Expression vectors; Intein-based vectors; Inclusion bodies; Methodologies to reduce formation of inclusion bodies; Baculovirus and pichia vectors system, Yeast vectors, Shuttle vectors |
| **Unit-3: Cloning Methodologies** **7 hours** |
| Insertion of Foreign DNA into Host Cells; Transformation; Construction of libraries; Isolation of mRNA and total RNA; cDNA and genomic libraries; cDNA and genomic cloning; Expression cloning; Jumping and hopping libraries |
| **Unit-4: PCR and Its Applications** **7 hours** |
| Primer design; Fidelity of thermostable enzymes; DNA polymerases; Types of PCR – multiplex, nested, reverse transcriptase, real time PCR, Site specific mutagenesis; PCR in molecular diagnostics; Viral and bacterial detection; PCR based mutagenesis, |
| **Unit-5: Sequencing methods and other techniques** **7 hours** |
| Sequencing methods; Enzymatic DNA sequencing; Chemical sequencing of DNA; |

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|---|
| Automated DNA sequencing; RNA sequencing; Chemical Synthesis of oligonucleotides; |
| **Unit-6: Genetic engineering techniques 5 hours** |
| Southwestern and Far-western cloning; Protein-protein interactive cloning and Yeast two hybrid system; Phage display; Principles in maximizing gene expression; Mutation detection: Molecular Markers; PTT (Protein Truncation Test); Introduction of DNA into mammalian cells; Transfection techniques; Gene silencing techniques; Introduction to siRNA; siRNA technology; Micro RNA; |

**Suggested Readings**


1. S.B. Primrose, R.M. Twyman and R.W.Old; Principles of Gene Manipulation. 6th Edition, S.B.University Press, 2001.
2. J. Sambrook and D.W. Russel; Molecular Cloning: A Laboratory Manual, Vols 1-3, CSHL, 2001.
3. Brown TA, Genomes, 3rd ed. Garland Science 2006
4. Nicholl DS. An introduction to genetic engineering. Cambridge University Press; 2008 May 29.
5. Glick BR, Patten CL. Molecular biotechnology: principles and applications of recombinant DNA. John Wiley & Sons; 2017 Jun 1.


| **Name of The Course** | **Immunotechnology** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT3002** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**

Students will get exposure about the fundamental concepts and anatomy of the immune system, vaccinology and clinical Immunotechnology.

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of fundamental concepts and anatomy of the immune system |
| CO2 | Understand about the Immune responses generated by B and T lymphocytes |
| CO3 | Understand about the Antigen-antibody interactions |
| CO4 | Understand about the Vaccinology |
| CO5 | Understand about the Clinical Immunology |
| CO6 | Analyze the Clinical transplantation, Tumor immunology & Immunodeficiency |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Immunology-fundamental concepts** | **7 hours** |
|---|---|
| Components of innate and acquired immunity; Phagocytosis; Complement and Inflammatory responses; Haematopoesis; Organs and cells of the immune system- primary and secondary lymphoid organs; Lymphatic system; Lymphocyte circulation; Mucosal and Cutaneous associated Lymphoid tissue (MALT & CALT); Mucosal Immunity; Antigens - immunogens, haptens; Major Histocompatibility Complex - MHC genes, MHC and immune responsiveness and disease susceptibility, HLA typing | |
| **Unit-2: Immune responses generated by B and T lymphocytes** | **7 hours** |
| Immunoglobulins-basic structure, antigenic determinants; Multigene organization of immunoglobulin genes; B-cell receptor; Immunoglobulin superfamily; Principles of cell signaling; Immunological basis of self –non-self discrimination; memory; B cell maturation, activation and differentiation; Generation of antibody diversity; T-cell maturation, activation and differentiation and T-cell receptors; Functional T Cell Subsets; Cell-mediated immune responses, ADCC; Cytokines-properties, receptors and therapeutic uses; Antigen processing and presentation, Hapten-carrier system | |
| **Unit-3: Antigen-antibody interactions** | **7 hours** |
| Precipitation, agglutination and complement mediated immune reactions; Advanced immunological techniques - RIA, ELISA, | |

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|---|
| Western blotting, ELISPOT assay, immunofluorescence, flow cytometry and immunoelectron microscopy; Surface plasmon resonance, Biosensor assays for assessing ligand –receptor interaction, CMI techniques- lymphoproliferation assay, Mixed lymphocyte reaction |
| **Unit-4: Vaccinology** **7 hours** |
| Active and passive immunization; Live, killed, attenuated, sub unit vaccines; Vaccine technologyRole and properties of adjuvants, recombinant DNA and protein based vaccines, plant-based vaccines, reverse vaccinology; Peptide vaccines, conjugate vaccines; Antibody genes and antibody engineering- chimeric and hybrid monoclonal antibodies; Catalytic antibodies and generation of immunoglobulin gene libraries. |
| **Unit-5: Clinical Immunology** **7 hours** |
| Immunity to Infection : Bacteria, viral, fungal and parasitic infections (with examples from each group); Hypersensitivity – Type I-IV; Autoimmunity; Types of autoimmune diseases; Mechanism and role of CD4+ T cells; MHC and TCR in autoimmunity; Treatment of autoimmune diseases; |
| **Unit-6 Clinical transplantation, Tumor immunology & Immunodeficiency 5 hours** |
| Transplantation – Immunological basis of graft rejection; Clinical transplantation and immunosuppressive therapy; Tumor immunology – Tumor antigens; Immune response to tumors and tumor evasion of the immune system, Cancer immunotherapy; Immunodeficiency-Primary immunodeficiencies, Acquired or secondary immunodeficiencies. |

**Suggested Readings:**


1. Kuby, RA Goldsby, Thomas J. Kindt, Barbara, A. Osborne Immunology, 6th Edition, Freeman, 2002.
2. Brostoff J, Seaddin JK, Male D, Roitt IM., Clinical Immunology, 6th Edition, Gower Medical Publishing,2002.
3. Janeway et al., Immunobiology, 4th Edition, Current Biology publications., 1999
4. Paul, Fundamental of Immunology, 4th edition, Lippencott Raven, 1999.
5. Goding, Monoclonal antibodies, Academic Press. 1985


| | | | | |
|---|---|---|---|---|
| **Name of The** | **Bioinstrumentation-II** | | | |
| **Course Code** | **BMBT3003** | | | |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50 % marks in aggregate. | | | |
| Corequisite | Basic knowledge of biology | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**: Students are able to apply knowledge of Centrifugation, Cytometry techniques, Radioactivity and Biomedical instrumentation.

**Course Outcomes**

| | |
|---|---|
| CO1 | Demonstrate different types of Centrifugation techniques |
| CO2 | Illustrate various kinds of Advanced Techniques |
| CO3 | Describe the principle and applications of various Cytometry techniques. |
| CO4 | Evaluate the different types of Biomedical instrumentation. |
| CO5 | Undersatand the principle of Radioactivity. |
| CO6 | Analyze the Radioactivity applications |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

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|---|
| **UNIT I Centrifugation 7 hours** |
| Centrifugation Basic principles; Mathematics & theory (RCF, Sedimentation coefficient etc); Types of centrifuge - Microcentrifuge, High speed & Ultracentrifuges; Preparative centrifugation; Differential & density gradient centrifugation; Applications (Isolation of cell components); Analytical centrifugation; Determination of |

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| molecular weight by sedimentation velocity & sedimentation equilibrium methods |
| **Unit-2 Advanced Techniques 7 hours** |
| Advanced Techniques: Protein crystallization; Theory and methods; API-electrospray and MADI-TOF; Mass spectrometry; Enzyme and cell immobilization techniques; DNA & Peptide Synthesis |
| **Unit-3 Cytometry 7 hours** |
| Manual Cell Counting: Counting chamber, Plating and CFU counting, Automated Cell Counting: Electrical resistance, Flow cytometry; Stereologic cell counting, blood cell counter |
| **Unit-4 Biomedical instrumentation 7 hours** |
| Basic transducer principles: active and passive transducers, transducers for biomedical applications; origin of bio potential and its propagation, sources of bioelectric potentials, electrocardiogram, electro encephalogram, electromyogram and other bioelectric potentials. Bio potential Electrodes: types of electrodes surface, needle and microelectrodes, biochemical transducers |
| **Unit-5 Radioactivity 7 hours** |
| Radioactive & stable isotopes; Pattern and rate of radioactive decay; Units of radioactivity; Measurement of radioactivity; Geiger-Muller counter; Solid & Liquid scintillation counters (Basic principle, instrumentation & technique); |
| **Unit-6 Radioactivity applications 5 hours** |
| Brief idea of radiation dosimetry; Cerenkov radiation; Autoradiography; Measurement of stable isotopes; Falling drop method; Applications of isotopes in biochemistry; Radiotracer techniques; Distribution studies; Isotope dilution technique; Metabolic studies; Clinical application; Radioimmunoassay |

**Suggested Readings:**


1. Physical Biochemistry: Principles and Applications (2010) 2nd ed., Sheehan, D., Wiley Blackwell (West Sussex), ISBN:978-0-470-85602-4 / ISBN:978-0-470-85603-1.
2. Physical Biochemistry: Applications to Biochemistry and Molecular Biology (1982) 2nd ed., Freifelder, D., W.H. Freeman and Company (New York), ISBN:0-7167-1315-2 / ISBN:0-7167-1444-2.
3. An Introduction to Practical Biochemistry (1998) 3rd ed., Plummer D. T., Tata McGraw Hill Education Pvt. Ltd. (New Delhi), ISBN:13: 978-0-07-099487-4 / ISBN:10: 0-07-099487-0


| **Name of The Course** | **Pharmacology and Toxicology** | | | | |
|---|---|---|---|---|---|
| **Course Code** | **BMBT3004** | | | | |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50 % marks in aggregate | | | | |
| Corequisite | Basic knowledge of chemistry and biology | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

**Course Objectives**: Students are able to apply knowledge of toxicology and pharmacologyin drug designing and application of knowledge of drug action can be used in research analysis and drug development.

**Course Outcomes**

| | |
|---|---|
| CO1 | Explain the basic concepts xenobiotics |
| CO2 | Analyze Toxic agents |
| CO3 | Illustrate the basic concept of General Pharmacology |
| CO4 | Interpret Pharmacokinetics and Pharmacodynamics of drugs |
| CO5 | Discuss the Classification of drugs and its mechanism. |
| CO6 | Examine the toxicity evaluation methods |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1 Fate of xenobiotics in human body 7 hours** |
|---|
| Xenobiotic compounds, xenobiotic tolerance,Metabolism of xenobiotics (biotransformation, Phase- I reactions including |

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|---|
| oxidations, hydrolysis, reductions and phase II conjugation reactions). |
| **Unit-2 Toxic agents 7 hours** |
| Human exposure, mechanism of action and resultant toxicities of the following xenobiotics: Metals: lead, arsenic, Pesticides: organophosphates, carbamates, organochlorine, bipyridyl compounds and anticoagulant pesticides. |
| **Unit-3 General Pharmacology 7 hours** |
| Nature and Source of drugs, Routes of drug administration and their advantages, receptor and receptor subtypes. |
| **Unit-4 Pharmacokinetics and Pharmacodynamics 7 hours** |
| Absorption, Distribution, Metabolism and Excretion (ADME) of drugs, bioavailability, Drug-drug interactions. Mechanism of drug action,Factors affecting drug action. |
| **Unit-5 Classification of drugs: 7 hours** |
| Mechanism of General anesthesia,Anti-inflammatory and analgesic drugs.Antimicrobial chemotherapeutic drugs. |
| **Unit-6 Evaluation of toxicity 5 hours** |
| Various types of dose response relationships, assumptions in deriving dose response, LD50, LC50, TD50 and therapeutic index. |

**Suggested Readings**:


1. Essentials of Medical Pharmacology, 7thedition (2010), K.D. Tripathi, Jaypee Brothers, ISBN: 9788184480856.
2. Pharmacology, 7th edition (2011), H.P. Rang, M.M. Dale, J.M. Ritter and P.K. Moore, Churchill Livingstone. ISBN: 9780702045042.
3. Hand book of Experimental Pharmacology, 4thedition (2012), S.K. Kulkarni, VallabhPrakashan, 2012. ISBN 13: 9788185731124.
4. Introduction to Toxicology, 3rd edition (2001), John Timbrell, Taylor and Francis Publishers. ISBN-13: 978-0415247627.
5. Cassarett and Doull‟s “Essentials of Toxicology”, 2nd edition (2010), Klaassen and Whatkins, McGraw Hill Publisher. ISBN-13: 978-0071622400.
6. Principles of Toxicology, 2nd edition (2006), Stine Karen and Thomas M Brown, CRC Press.ISBN-13: 978-0849328565.


# Semester IV

| | | | | | |
|---|---|---|---|---|---|
| Name of Thecourse | **Medical Microbiology** | | | | |
| Course Code | **BMBT4001** | | | | |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50 % marks in aggregate | | | | |
| Corequisite | Basic knowledge of microbiology | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

**Course Objectives**: Students are able to understand the Infections of the Gastrointestinal Tract, Respiratory system, Pyrexial Illness, Nervous System, and Sexually Transmitted Diseases and Congenital Infections

**Course Outcomes**

| | |
|---|---|
| CO1 | Interpret the Infections of the Gastrointestinal Tract. |
| CO2 | Explain the Infections of the Respiratory system. |
| CO3 | Understand the Pyrexial Illness. |
| CO4 | Examine the infections of Nervous System. |
| CO5 | Analyze the pathophysiology of Sexually Transmitted Diseases and Congenital Infections. |
| CO6 | Analyze the pathophysiology of Congenital Infections |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1 Infections of the Gastrointestinal Tract 7 hours** |
|---|
| Amoebiasis; Giardiasis and cryptosporidiosis; Intestinal infection by nematodes; Intestinal infection by cestodes (taeniasis and H.nana infection); Trematodes; Bacterial food poisoning(toxic and infective); E.coli Diarrhoea; Cholera; Bacillary dysentery; Hepatitis |
| **Unit-2 Infections of the Respiratory system 7 hours** |
| Streptococcal infections; Viral infections; Diphtheria; Whooping cough; Bacterial pneumonias (Haemophilus and GNB, Pneumococcus/Legionella/ etc); Tuberculosis, COVID-19, MERS |
| **Unit-3 Pyrexial Illness 7 hours** |
| Malaria; Kala-azar; Leishmaniasis; Filaria; Enteric fever; Brucellosis; Rickettsial diseases; Leptospirosis and relapsing fever; Viral Hemorragic fever |
| **Unit-4 Infections of the Nervous System 7 hours** |
| Viral encephalitis and Aseptic meningitis; Rabies; Cysticercosis and other CNS parasitic infections; Tetanus |
| **Unit-5 Sexually Transmitted Diseases 7 hours** |
| Herpes Simplex virus infections; HIV infection and AIDS; Chlamydial infection; Syphilis; Mycoplasma and Ureaplasma infection; Gonorrhea and other bacterial STD |
| **Unit-6 Congenital Infections 5 hours** |
| Congenital viral infections; Toxoplasmosis; Bacterial Sepsis and Meningitis |

**Suggested Readings**


4. Betty Forbes, Daniel Sahm, Alice Weinfield, Bailey-Scott's Diagnostic Microbiology, 12th Edition, Mosby. 2007.
5. 2. Gerald Collee J, Andrew G Fraser, Barrie P Marmion, Mackie and McCartney's Practical Medical Microbiology, Elsevier. 2006.
6. 3. Elmer W Koneman et al., Koneman's, Color Atlas and Text Book of Diagnostic Microbiology, 6th Edition, Lippincott Williams and Wilkins,2005.


| **Name of The Course** | **Fundamentals of Bioinformatics** | | | | |
|---|---|---|---|---|---|
| **Course Code** | **BMBT4002** | | | | |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50 % marks in aggregate. | | | | |
| Corequisite | Students should have understanding of general biology, including a basic knowledge of the computer science. | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

**Course Objectives**: Students are able to understand the basic concept of bioinformatics.

**Course Outcomes**

| | |
|---|---|
| CO1 | Describe the Introduction of Computer Fundamentals |
| CO2 | It Interpret the Introduction of Bioinformatics and Biological Databases |
| CO3 | Demonstrate Sequence Alignments, Phylogeny and Phylogenetic trees |
| CO4 | Evaluate Genome organization and analysis |
| CO5 | EvaluateProtein Structure Predictions |
| CO6 | Analyze the Biomolecular Simulations |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1 Introduction To Computer Fundamentals 7 hours** |
|---|
| RDBMS - Definition of relational database, Mode of data transfer (FTP, SFTP, SCP), advantage of encrypted data transfer. |

| **Unit-2 Introduction To Bioinformatics And Biological Databases 7 hours** |
|---|
| Biological databases - nucleic acid, genome, protein sequence and structure, gene expression databases, Database of metabolic pathways, Mode of data storage - File formats - FASTA, Genbank and Uniprot, Data submission & retrieval from NCBI, EMBL, DDBJ, Uniprot, PDB. |
| **Unit-3 Sequence Alignments, Phylogeny And Phylogenetic Trees 7 hours** |
| Local and Global Sequence alignment, pairwise and multiple sequence alignment. Scoring an alignment, scoring matrices, PAM & BLOSUM series of matrices. Types of phylogenetic trees, Different approaches of phylogenetic tree construction -UPGMA, Neighbour joining, Maximum Parsomony, Maximum likelihood. |
| **Unit-4 Genome Organization And Analysis 7 hours** |
| Diversity of Genomes: Viral, prokaryotic & eukaryotic genomes; Genome, transcriptome, proteome, 2-D gel electrophoresis, Maldi Toff spectroscopy; Major features of completed genomes: *E.coli, S.cerevisiae, Arabidopsis,* and Human. |
| **Unit-5 Protein Structure Predictions 7 hours** |
| Hierarchy of protein structure - primary, secondary and tertiary structures, modelling; Structural Classes, Motifs, Folds and Domains; Protein structure prediction in presence and absence of structure template; Energy minimizations and evaluation by Ramachandran plot Protein structure and rational drug design. |
| **Unit-6 Biomolecular Simulations 5 hours** |
| Force field and energy landscape; Minimization and alogrithms; Molecular dynamics; Free energy calculations; Membrane simulations |

**Suggested Readings:**

1. Saxena Sanjay (2003) A First Course in Computers, Vikas Publishing House
2. Pradeep and Sinha Preeti (2007) Foundations of Computing, 4th ed., BPB Publications
3. Lesk M.A.(2008) Introduction to Bioinformatics . Oxford Publication, 3rd International Student Edition
4. Rastogi S.C., Mendiratta N. and Rastogi P. (2007) Bioinformatics: methods and applications, genomics, proteomics and drug discovery, 2nd ed. Prentice Hall India Publication
5. Primrose and Twyman (2003) Principles of Genome Analysis & Genomics. Blackwell

| **Name of The Course** | **Animal Biotechnology** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT4003** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:
Students will get exposure about the tools and techniques used in animal biotechnology.

**Course Outcomes**:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts Animal cell culture |
| CO2 | Understand about the Culture medium and assay |
| CO3 | Analyze the Culture assay |
| CO4 | Understand about the cell culture techniques |
| CO5 | Understand about the concepts of Animal propagation |
| CO6 | Understand about the Genetic modification in Medicine |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Basics Concepts** | **7 hours** |
|---|---|
| Animal Cell Culture: Historical Background, importance of and progress in Animal Cell Culture Technology, Application of animal cell culture. Equipments, materials, culture vessels for animal cell culture technology. Primary and established cell line cultures, Culturing and Sub-Culturing of Animal Cells. | |
| **Unit-2: Culture medium** | **7 hours** |
| Introduction to the balanced salt solutions and simple growth medium. Chemical, physical and metabolic functions of different constituents of | |

| |
|---|
| culture medium, Role of carbon dioxide, Role of serum and supplements, Serum & protein free defined media and their application. |
| **Unit-3: Culture assay**<br>**5 hours** |
| Measurement of viability, cytotoxicity and apoptosis in cell culture. |
| **Unit-4: cell culture techniques** **7 hours** |
| Biology and characterization of cultured cells - cell adhesion, proliferation, differentiation, morphology of cells and identification. Primary cell culture techniques - mechanical disaggregation, enzymatic disaggregation, separation of viable and non-viable cells. Types of cell lines, maintenance of cell lines. Measuring parameters of growth. |
| **Unit-5: Animal propagation** **7 hours** |
| Animal propagation – IVF, Artificial insemination, Conservation Biology – Embryo transfer techniques. Transgenic Animals. Introduction to Stem Cell Technology and its applications. Animal diseases need help of Biotechnology – Foot-and mouth disease, Coccidiosis, Trypanosomiasis, Theileriosis |
| **Unit-6: Genetic modification in Medicine** **7 hours** |
| Genetic modification in Medicine - Gene knockouts and Gene Therapy; Gene replacement; Gene targeting;, types of gene therapy, vectors in gene therapy, molecular engineering, human genetic engineering, problems & ethics. |

**Suggested Readings**


1. S.B. Primrose, R.M. Twyman and R.W.Old; Principles of Gene Manipulation. 6th Edition, S.B.University Press, 2001.
2. J. Sambrook and D.W. Russel; Molecular Cloning: A Laboratory Manual, Vols 1-3, CSHL, 2001.
3. Brown TA, Genomes, 3rd ed. Garland Science 2006
4. Nicholl DS. An introduction to genetic engineering. Cambridge University Press; 2008 May 29.
5. Glick BR, Patten CL. Molecular biotechnology: principles and applications of recombinant DNA. John Wiley & Sons; 2017 Jun 1.


| **Name of The Course** | **Fundamentals of Clinical Research** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT4004** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives: Students will be exposed to Clinical Research and their requirements, Pharmaceutical Industry, Bioavailability and Bioequivalence Studies.

**Course Outcomes**

| | |
|---|---|
| **CO1** | Historical Aspects of clinical research, clinical research terminologies |
| **CO2** | Phases of Clinical Trial and Types of Clinical Trial including Virtual Clinical Trials |
| **CO3** | Pharmaceutical Industry and concepts of Intellectual Property Rights |
| **CO4** | Modules of International Conference on Hormonization (Quality, Safety, Efficacy and Miscellaneous) and E6 Overview |
| **CO5** | Drug Regulation and Evidence based medicine |
| **CO6** | Analysis of Evidence-based medicine |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| |
|---|
| **Unit I: Basic Introduction to Clinical Research 7 Hours** |
| Overview, Opportunities & Career options in Clinical Research, Glossary of GCP. Historical Aspects of clinical research, Brief description of different phases, Stakeholders in clinical research, Need/Area for clinical research. |
| **Unit-2 Phases and Types of Clinical Trials 7 Hours** |
| Introduction to Clinical Trials – Phases of Clinical Trials, Types of Clinical Trials, Randomized/Non |

| |
|---|
| randomized Clinical Trial, Virtual-clinical trials, Drug discovery and development. |
| **Unit-3 Pharmaceutical Industry & globalization 7 Hours** |
| Overview of global and local players, Intellectual Property Rights: Introduction, Scope, Objectives and concepts of IPR, Tangible & Intangible property, scope & nature of patents, copyrights, trademark, Indian Patent Act 1970, practical aspects of patent filing. |
| **Unit-4: ICH Introduction 7 Hours** |
| ICH Introduction, Origin, Organization, Structure, Modules of ICH (Quality, Safety, Efficacy and Miscellaneous), E6 Overview |
| **Unit-5: Introduction to Indian GCP and ICMR 5 Hours** |
| Indian- good clinical practice, Overview of ICMR |
| **Unit-6: Evidence-based medicine 7 Hours** |
| Need for evidence based approach in making decisions in family medicine; difference between evidence based medicine and evidence based health care; classification of evidence – information levels; 5 steps process for use of evidence oriented approach in family medicine |

**Suggested Readings**


7. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., Dupin-Spriet T., Simon P. Publisher: Karger
8. Indian GCP Guideline.
9. Schedule Y: Drug and Cosmetic Act 1940
10. Design and Analysis of Clinical Trials: Concepts and Methodologies, 3rd Edition. SheinChung Chow, Jen-Pei Liu. Publisher: Wiley.
11. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Publisher: Wiley-Blackwell


| **Name of The Course** | **Drug Discovery and Development** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT4005** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**
Students will get exposure about Drug Discovery and Development

**Course Outcomes**:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Drug Discovery and Development |
| CO2 | Understand about the Pre-Clinical Studies |
| CO3 | Understand about Bioassays |
| CO4 | Understand about the Drug designing |
| CO5 | Understand about the Methods and Process of Drug discovery |
| CO6 | Understand about the Non Clinical Drug Development |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Introduction to Drug development** | **7 hours** |
|---|---|
| Need for a new Drug, Target identification, lead identification, Sources of new drugs: synthetic, natural, endogenous, peptides; compounds for screening as a potential drug, Drug Discovery & Drug development process. In vivo, in vitro and in silico studies. Animal models of diseases. | |
| **Unit-2: Pre-Clinical Studies** | **7 hours** |
| Importance of Pre-Clinical studies, Steps involved in Pre-clinical studies, Types of Pre-Clinical Studies, Introduction to toxicology, Organ specific toxicity, Toxicity Studies. | |
| **Unit-3: Bioassays** | |
| Bioassays; Biochemical, Molecular, Behavioural & Physiological parameter analysis, Pharmacokinetics, Pharmacology, Pharmacodynemics, Tissue distribution study | |
| **Unit-4: Drug designing** | **7 hours** |
| Drug design-Ligand based, Structure based, target-centered drug design: DNA, RNA and Protein based drug designing, Structure Activity Relationship (SAR), Quantitative Structure Activity Relationship (QSAR), Computer assisted drug designing (CADD) | |
| **Unit-5: Methods and Process of Drug discovery** | **7 hours** |
| High Through Put Screening (HTS): Introduction, Advantages and Disadvantages, Uses, | |

| | |
|---|---|
| Methodology; Combinatorial Chemistry, methods and processes; Lead optimization techniques | |
| **Unit-6: Non Clinical Drug Development** | **5 hours** |
| GLP, GMP, GCP; submission of IND, NDA, ANDA | |

**Suggested Readings**


6 Preclinical Drug Development, Edited by Mark Rogge, David R. Taft, Second Edition, 25th Sep 2009.

7 Hill RG. Drug Discovery and Development-E-Book: Technology in Transition. Elsevier Health Sciences; 2012 Jul 20.

8 Choudhary MI, Thomsen WJ. Bioassay techniques for drug development. CRC Press; 2001 Oct 4.

9 Klebe G. Drug Design: Methodology, concepts, and mode-of-action. Heidelberg, Germany: Springer; 2013 Jul 10.

10 Armstrong JD, Hubbard RE, Farrell T, Maiguashca B, editors. Structure-based drug discovery: an overview. Royal Society of Chemistry; 2006


# Semester V

| **Name of The Course** | **Biomaterials & Tissue Engineering** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT5001** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 4 | 0 | 0 | 4 |

**Course Objectives**:
Students will get exposure about natural and synthetic polymers,

**Course Outcomes**:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the Fundamentals of biomaterials science |
| CO2 | Analyze the Biocompatibility of biomaterials |
| CO3 | Understand about the Biomaterials Surfaces |
| CO4 | Understand about the Biomaterials for Organ Replacement |
| CO5 | Understand about the Tissue Engineering |
| CO6 | Analyze the FDA requirements of medical devices |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Fundamentals of biomaterials science** | **7 hours** |
|---|---|
| Fundamentals of biomaterials science. Concept of biocompatibility. Assessment of biocompatibility of biomaterials. Classes of biomaterials used in medicine, basic properties, medical requirements and clinical significance. Disinfection and sterilization of biomaterials. | |
| **Unit-2 Biocompatibility of biomaterials 5 hours** | |
| Host reactions to biomaterials: biocompatibility, implant associated infection; Testing of biomaterials: in vitro assessment, in vivo assessment, blood materials interactions | |
| **Unit-3: Biomaterials Surfaces** | **7 hours** |
| Surface (vs. Bulk) Structure and Properties, Physico-chemical properties of biomaterials: mechanical (elasticity, yield stress, ductility, toughness, strength, fatigue, hardness, wear resistance), tribological (friction, wear, lubricity), morphology and texture, physical (electrical, optical, magnetic, thermical), chemical and biological properties. | |
| **Unit-4: Biomaterials for Organ Replacement** | **7 hours** |
| Biomaterials for Organ Replacement; Organ Replacement Therapies; Mechanical Properties; Bone Substitutes; Biodegradable polymers; Design of materials for biomedical application: Cardiovascular, dental implants, orthopedic application, skin, ophthalmologic applications, wound healing, sutures; Failure analysis of medical devices and implants | |
| **Unit-5: Tissue Engineering** | **7 hours** |
| Tissue Engineering, Cell Types; Approaches: In vitro, In vivo, Ex vivo/Cell Encapsulation, Scaffolds: Design and Fabrication; Case Examples: Artificial Pancreas, Cartilage, Nerve Regeneration. Bioreactors for Tissue Engineering | |
| **Unit-6: FDA requirements of medical devices** | **7 hours** |

| |
|---|
| FDA requirements, standards on the biological evaluation of medical devices (ISO-10993) and implications to applications in human. Practical aspects of biomedical devices: manufacturing, storage quality, regulatory and ethical issues, price of implants and allocation of resources. |

**Suggested Readings**

1 "Tissue Engineering", Bernhard O. Palsson, Sangeeta N. Bhatia, Pearson Prentice Hall Bioengineering.

2 "Nanotechnology and Tissue engineering - The Scaffold", Cato T. Laurencin, Lakshmi S. Nair, CRC Press

| **Name of The Course** | **Nanobiotechnology and Biosensors** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT5002** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:
Students will understand about the Nanobiotechnology and Biosensors.

**Course Outcomes**:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the nanobiotechnology |
| CO2 | Understand the Biosensors |
| CO3 | Applications of biosensors |
| CO4 | Understand the Biological nanoparticles production |
| CO5 | Understand the Nanobiotechnological applications in health and disease |
| CO6 | Understand about the Nanobiotechnological applications in Environment and food |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| | |
|---|---|
| **Unit-1: Introduction to nanobiotechnology** | **7 hours** |
| Development of nanobiotechnology - timelines and progress, overview; Nanomaterial in biotechnology - nanoparticles, quantum dots, nanotubes and nanowires | |
| **Unit-2: Biosensors** | **7 hours** |
| Chemoreceptors, Baroreceptors, Touch receptors; Biosensors; Working Principle and Types, - molecular recognition elements, transducing elements. | |
| **Unit-3 Applications of biosensors 5 hours** | |
| Enzyme-based biosensors, e.g., the blood glucose sensor; Array-based DNA "biochip" sensors with fluorescence detection; Applications of molecular recognition elements in nanosensing of different analytes; Application of various transducing elements as part of nanobiosensors. | |
| **Unit-4: Biological nanoparticles production** | **7 hours** |
| Biological nanoparticles production - plants and microbial. Miniaturized devices in nanobiotechnology - types and applications, lab on a chip concept. | |
| **Unit-5: Nanobiotechnological applications in health and disease** | **7 hours** |
| Nanobiotechnological applications in health and disease - infectious and chronic. | |
| **Unit-6: Nanobiotechnological applications in Environment and food** | **7 hours** |
| Nanobiotechnological applications in Environment and food - detection and mitigation | |

**Suggested Readings**

1. Nanobiotechnology: Concepts, Applications and Perspectives (2004), Christof M.Niemeyer (Editor), Chad A. Mirkin (Editor), Wiley VCH.
2. Nanobiotechnology - II more concepts and applications. (2007) - Chad A Mirkin and Christof M. Niemeyer (Eds), Wiley VCH.

| **Name of The Course** | **Industrial Bioprocess Technology** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT5003** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 4 | 0 | 0 | 4 |

**Course Objectives**:
Students will understand about the Industrial Bioprocess Technology.

**Course Outcomes**:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the Introduction to bioprocess technology |
| CO2 | Understand the Bioprocess operations |
| CO3 | Analyze the concept of Mass transfer |
| CO4 | Understand the Designing of bioprocess vessels |
| CO5 | Understand the upstream and downstream processing |
| CO6 | Understand about the Production of industrial chemicals |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Introduction to bioprocess technology** | **7 hours** |
|---|---|
| Introduction to bioprocess technology. Range of bioprocess technology and its chronological development. Basic principle components of fermentation technology. Types of microbial culture and its growth kinetics– Batch, Fedbatch and Continuous culture. | |
| **Unit-2: Bioprocess operations** | **7 hours** |
| Rate equations for enzyme kinetics, simple and complex reactions. Inhibition kinetics; effect of pH and temperature on rate of enzyme reactions. Mathematical derivation of growth kinetics, mathematical derivations of batch and continuous culture operations; single stage CSTR; | |
| **Unit-3 Mass transfer 5 hours** | |
| Mass transfer in aerobic fermentation; Introduction to oxygen requirement in bioprocess; mass transfer coefficient; factors affecting KLa. Factors depending on scale up principle and different methods of scaling up. | |
| **Unit-4: Design of bioprocess vessels** | **7 hours** |
| Design of bioprocess vessels- Significance of Impeller, Baffles, Sparger; Types of culture/production vessels- Airlift; Cyclone Column; Packed Tower and their application in production processes. Bioprocess measurement and control system with special reference to computer aided process control. | |
| **Unit-5: upstream and downstream processing** | **7 hours** |
| Principles of upstream processing – Media preparation, Inocula development and sterilization. Introduction to downstream processing, product recovery and purification. Effluent treatment. Centrifugation, filtration of fermentation broth, ultra centrifugation, liquid extraction, ion-exchange recovery of biological products. Microbial production of ethanol, amylase, lactic acid and Single Cell Proteins. | |
| **Unit-6: Production of industrial chemicals** | **7 hours** |
| Production of industrial chemicals, biochemicals and chemotherapeutic products. Biofuels: Biogas, Ethanol, butanol, hydrogen, biodiesel, microbial electricity. Microbial products of pharmacological interest, steriod fermentations and transformations. Metabolic engineering of secondary metabolism for highest productivity; antibiotic biosynthetic pathways. Enzyme and cell immobilization techniques in industrial processing. | |

**Suggested Readings:**


1. Casida LE. (1991). Industrial Microbiology. 1st edition. Wiley Eastern Limited.
2. Crueger W and Crueger A. (2000). Biotechnology: A textbook of Industrial Microbiology. 2nd edition. Panima Publishing Co. New Delhi.
3. Patel AH. (1996). Industrial Microbiology. 1st edition, Macmillan India Limited.
4. Stanbury PF, Whitaker A and Hall SJ. (2006). Principles of Fermentation Technology. 2nd edition, Elsevier Science Ltd


| **Name of The Course** | **Regulatory affairs and Ethics in Clinical Research** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT5004** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:
Students will get exposure about the ethical concepts clinical research and the process of evolution of regulatory control in clinical trial

**Course Outcomes**:

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the ethical aspects important to sound clinical research |
| CO2 | Understand about the IRB/IEC, Independent Ethic committees, Ethic review |
| CO3 | Understand about the operational imperatives of Good Clinical Practices |
| CO4 | Understand about the regulatory control, ICH-GCP, ICMR requirement |
| CO5 | Understand about the international regulatory bodies and guidelines |
| CO6 | Analyze the IND and NDA application process |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Ethic in clinical research** | **7 hours** |
|---|---|
| Evolution of ethic 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 a investigator, compensation to subjects/patients for clinical trial related injuries | |
| **Unit-2: Overview of IRB/IEC/ERB** | **7 hours** |
| Independent Ethic committees, Ethic review procedures, importance of inform consent document, patient information sheet, and inform consent form, Fraud and misconduct, detection of fraud in clinical research. Ethics in academia, violation of ethic in clinical research, HIPAA | |
| **Unit-3: Evolution of regulatory control** | **7 hours** |
| Evolution of regulatory control: An international comparison, Pure food and drug act, drug and cosmetic act 1945, thalidomide disaster, Kafauvers Harris amendment act, Waxman hatch act, Evolution of ICH, NICE. Introduction to ICH-International Conference on Harmonization of technical requirements for registration of Pharmaceuticals for human use guidelines Milestones in the evaluation of GCP | |
| **Unit-4: Applicable GCP Guidelines** | **7 hours** |
| International Conference on Harmonization of technical requirements for registration of Pharmaceuticals for human use guidelines (ICH-GCP), Indian Council Of Medical Research- Ethical Guidelines for Biomedical Research on Human participants (ICMR), Indian Good Clinical Practices | |
| **Unit-5: International Regulatory bodies and Guidelines** | **7 hours** |
| US Food and Drug Administration(USFDA): 21CFR 50,316,314The FDA and Food Drug and Cosmetics Act, New drug development and approval : the principal steps. India: Regulatory laws, Schedule Y, registration of new drugs, requirements for registration, regulatory environment and practices, Indian GCP, CTRI<br><br>Medicines and Healthcare Products Regulatory Agency (MHRA): Overview of regulatory environment/ background, regulatory authorities, regulatory requirements and procedures. European Agency for Evaluation of medicinal Products(EMEA): National registration , the decentralized procedures, mutual recognition procedures. Brazil: Overview of regulatory affairs | |
| **Unit-6 IND and NDA 5 hours** | |
| IND Application :requirements forms , contents, application , Investigator IND, Treatment IND , Emergency use of IND. NDA application: contents , forms , review process, actions, Guidance documents for IND and NDA, Common Technical Document: Purpose , structure and contents | |

**Suggested Readings**:


1. Guide to Clinical Trials (Volume-I &II), ICRI
2. Good Clinical Practice by Josef Kolman, Paul Meng
3. 1. Guideline for Drug Regulatory Submissions by Sandy Welnberg
4. 2. International Pharmaceutical Registration by Alan A Chalmers

| | | | | | |
|---|---|---|---|---|---|
| **Name of The Course** | **Molecular Diagnostics & Therapeutics** | | | | |
| **Course Code** | **BMBT5005** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

**Course Objectives:**
Students will understand about the tools and techniques used in the molecular diagnosis & Therapeutics.

**Course Outcomes:**
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the basic concepts of host pathogen interactions and Biomarkers |
| CO2 | Understand the biochemical based diagnosis. |
| CO3 | Understand the DNA based diagnosis |
| CO4 | Understand the protein based diagnosis |
| CO5 | Understand the Cellular therapy |
| CO6 | Understand about the Recombinant therapy & Immunotherapy |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Host pathogen interactions and Biomarkers** | **7 hours** |
|---|---|
| Biomarkers- types and applications; Host pathogen interactions in disease process; Protective immune response in Bacterial, Viral and Parasitic diseases; Cancer; Inappropriate Immune response; Disease pathology and clinical spectrum; Clinical diagnosis of diseases; Molecular Genetics of the host and the pathogen | |
| **Unit-2: Biochemical based diagnosis** | **7 hours** |
| Biochemical disorders; Molecular techniques for analysis of these disorders; Assays for the Diagnosis of inherited diseases; Antibody based diagnosis; Monoclonal antibodies as diagnostic reagents; Production of monoclonal antibodies with potential for diagnosis; Diagnosis of bacterial, viral and parasitic diseases by using; ELISA and Western blot. | |
| **Unit-3: DNA based diagnosis** | **7 hours** |
| Aptamers; DNA sequencing and diagnosis; PCR and Array based techniques in diagnosis; Single nucleotide polymorphism and disease association; Two dimensional gene scanning. | |
| **Unit-4: Protein based diagnosis 5 hours** | |
| Protein Micro array; Present methods for diagnosis of Specific diseases like Tuberculosis, Malaria and AIDS; Ethics in Molecular Diagnosis | |
| **Unit-5: Cellular therapy** | **7 hours** |
| Cellular therapy; Stem cells: definition, properties and potency of stem cells; Sources: embryonic and adult stem cells; Concept of tissue engineering; Role of scaffolds; Role of growth factors; Role of adult and embryonic stem cells; Clinical applications; Ethical issues | |
| **Unit-6: Recombinant therapy & Immunotherapy** | **7 hours** |
| Recombinant therapy; Clinical applications of recombinant technology; Erythropoietin; Insulin analogs and its role in diabetes; Recombinant human growth hormone; Streptokinase and urokinase in thrombosis; Recombinant coagulation factors; Immunotherapy; Monoclonal antibodies and their role in cancer; Role of recombinant interferons; Immunostimulants; Immunosupressors in organ transplants; Role of cytokine therapy in cancers; Vaccines: types, recombinant vaccines and clinical applications | |

**Suggested Readings**:


7. Campbell, M.A and Heyer L.J., Discovering Genomics, Proteomics and Bioinformatics, 2nd Edition, CSHL Press, Pearson/Benzamin Cummings San Francisco, USA, 2007.
8. Andrew Read and Dian Donnai, New Clinical Genetics, Scion Publishing Ltd, Oxfordshire, UK, 2007.
9. James W Goding, Monoclonal antibodies: Principles and Practice, 3rd Edition, Academic Press, 1996.
10. Bernhard Palsson and Sangeeta N Bhatia, Tissue Engineering, 2nd Edition, Prentice Hall, 2004.
11. George Patrinos and Wilhelm Ansorage, Molecular Diagnostics, 1 st Edition, Academic Press, 2005.

12. Lela Buchingham and Maribeth L Flawsm, Molecular Diagnostics: Fundamentals, Methods and Clinical Applications, 1 st Edition, F A Davis Company, Philadelphia, USA, 2007.

# Electives

| **Name of The Course** | **Introduction to Healthcare** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT4006** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:
Introduction to Healthcare exposes a student to learn Healthcare system, Hospital Role, Infection control, and foundation of health.

**Course Outcomes**
On completion of this course the students will be able to understand

| | |
|---|---|
| **CO1** | Healthcare systems and Ethical Roles and Responsibilities of a Health Care Worker |
| **CO2** | Holistic Health and Controlling Infection, Mental Health, Nutrition, Controlling Infection |
| **CO3** | Foundation of health and healthcare system, Community Medicine and Hospitals |
| **CO4** | Introduction to Primary healthcare, state & district level including Municipal Corporations & Councils |
| **CO5** | Role of Hospital in healthcare system, National Rural and Urban Health Mission |
| **CO6** | Inventory Control & Purchase Management |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit I: Healthcare Systems**<br>**7 hours** |
|---|
| Careers in Health Care, Personal Qualities of a Health Care Worker/Health Care Providers, Measurement, Medical Terminology, Legal Obligations, Cultural Considerations, Medical Liability and Patient's Rights, Ethical Roles and Responsibilities of a Health Care Worker |
| **Unit II:Health Control**<br>**7 Hours** |
| Holistic Health, Mental Health, Nutrition, Controlling Infection, Measuring Vital Signs and other Clinical Skills, Injury and Prevention, First Aid/ CPR |
| **Unit III: Foundations of Health and Healthcare System 7 hours** |
| Concept of health & disease: Concept of Prevention, Preventive Medicine, History of Hospitals. Characteristics Hospitals as industry, Community Medicine & Hospitals |
| **Unit IV: Introduction to Primary Health Care**<br>**7 hours** |
| Definition, Principles, Functions, Evolution of Health Care System. Organisation of Health Services at central, state & district level including Municipal Corporations & Councils, Panchayat Raj institutions. Inter-sectoral linkages |
| **Unit V:Role of hospitals in health care system**<br>**7 hours** |
| National health policy, National Rural and Urban Health Mission. National Health Programmes. International Health Agencies, Concepts of family welfare, National Family Welfare programme. MCH and RCH programmes |
| Unit VI: Inventory Control & Purchase Management<br>5 **Hours** |
| Inventory Control & Purchase Management-meaning & significance. Purchasing & procurementPrinciples of sourcing, purchase methods & procedures, legal aspects of purchasing. Reference to Contract Act, Sale of Goods Act, Drug Control Act in respect to purchase activities. Import substitution |

**Suggested Readings:**

5. Health Care Reforms in India – Rajendra Pratap Gupta
6. Introduction to Health Care – SHARON B. BUCHBINDER & NANCY H. SHANKS

7. Innovation in Health Care Management- VK Singh n Paul Lillrank
8. India's Healthcare Industry – Lawton Robert Burns

| | |
|---|---|
| **Name of The Course** | **Evolutionary Biology** |
| **Course Code** | **BMBT4007** |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50% marks in aggregate. |
| Corequisite | Basic knowledge of evolution |
| Antirequisite | |
| | |
| | |

| L | T | P | C |
|---|---|---|---|
| 4 | 0 | 0 | 4 |

**Course Objectives**: Students are able to understand the significance of evolution and can work in geography laboratory, engage in research.

**Course Outcomes**

| | |
|---|---|
| CO1 | Explain the theories of organic evolution |
| CO2 | Analyze Evidence of Organic evolution |
| CO3 | Illustrate the basic concept Population genetics |
| CO4 | Interpret Products of evolutionary change |
| CO5 | Illustrate the Geological time scale. |
| CO6 | Analyze the concept of Genetic drift |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 30 | 30 | 50 | 100 |

**Course Content:**

| |
|---|
| **Unit- 1 Theories of organic evolution 7 hours** |
| Lamarckism, Darwinism, Development and concept of synthetic theory, Natural selection in action (industrial melanism, antibiotic and DDT resistance), type of natural selection; Stabilizing selection, Directional selection, Diversifying selection, cyclic selection, k selection and r selection, selection pressure |
| **Unit-2 Evidence of Organic evolution 7 hours** |
| Evidence of Organic evolution from morphology and comparative anatomy(tectology); Homology and homologous organs, types of homology; phylogenetic homology, sexual homology, serial homology. Analogy and analogous organs, Divergent evolution, Convergent evolution, vestigial organs, Evidence of evolution from Comparative embryology, recapitulation theory, Evidence from Palaeontology, Evidence from Biochemistry and physiology, Evidence from Zoogeography |
| **Unit-3 Population genetics 7 hours** |
| Concept of Deme, gene pool, gene frequency, genotype frequency, genetic equilibrium and Hardy Weinberg's law of equilibrium |
| **Unit-4 Products of evolutionary change 7 hours** |
| Species concept, speciation, phyletic speciation, quantum speciation, gradual speciation, allopatric speciation, sympatric speciation, parapatric speciation, Isolating mechanisms and modes of speciation. Adaptation and evolution: Structural adaptation, coadaptation-adaptation, k adaptation, Divergent evolution (adaptive radiation) adaptive radiation in finches, parallel evolution (convergent evolution) |
| **Unit-5 Geological time scale 7 hours** |
| The Eras, Azoic era, Archaeozoic era, Proterozoic area, Paleozoic era, Mesozoic era, Cenozoic era, Different periods and its characteristics, Ordovician period, Silurian period, Devonian period, Dinosaurs and its type distribution and extinction. |
| **Unit-6 Genetic drift 5 hours** |
| Genetic load and genetic death, mutational and segregation load, silent feature of Genetic drift, Sewall wright effect, Bottle neck phenomenon, founder effect, concept of polymorphism, balanced polymorphism, transient polymorphism. |

**Suggested Readings:**


1. Ridley, M. (2004) Evolution. III Edition. Blackwell Publishing
2. Barton, N. H., Briggs, D.E.G., Eisen, J. A., Goldstein, D. B. and Patel, N. H. (2007). Evolution. Cold Spring Harbour Laboratory Press.
3. Hall, B.K. and Hallgrimsson, B. (2008) Evolution. IV Edition. Jones and Bartlett Publishers

4. Pevsner, J. (2009) Bioinformatics and functional genomics. II Edition. Wiley-Blackwell
5. Rastogi, V.B. organic evolution.

| **Name of The Course** | **Designing Clinical Trials** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT4008** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:
Students will get exposure about the designing of clinical trial, methodology of designing and importance of designing.

**Course Outcomes**:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of designing & development |
| CO2 | Understand about the type of designing |
| CO3 | Understand about the designing in outcomes of clinical trials |
| CO4 | Understand about the different tools used in designing |
| CO5 | Understand about the evaluation of outcome |
| CO6 | Analyze the strategy of clinical trial design |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Introduction to clinical trial design** | **7 hours** |
|---|---|
| Overview and importance of clinical trial designing, title of study, terminologies, regulatory requirement for trial design, ethical consideration to develop clinical trial design | |
| Unit-**2: Fundamentals of clinical trial design** | **7 hours** |
| Objectives of clinical trial design, types of designs-observational, interventional, prospective, retrospective, single and multicentric, randomization, nonrandomization, crossover design, parallel design, comparative design, non-comparative design, single arm, multiple arm, appropriate hypotheses(superiority, inferiority, non-inferiority, equivalency). | |
| **Unit-3: Planning clinical trial design** | **7 hours** |
| Subject's recruitment, recruitment advertisement, and rule for subject withdrawal, eligibility of subject (inclusion and exclusion criteria), study procedure, recruitment period, treatment period, follow-up period, | |
| **Unit-4: Efficacy and safety assessment mechanisms** | **7 hours** |
| Objectives, definitions, Importance, description of efficacy methods and assessment parameters, baseline and endpoint measurements, description of safety and assessment methods, adverse event, serious adverse event, suspected adverse event, unexpected adverse event and reporting mechanisms. | |
| **Unit-5: Outcomes and analysis** | **7 hours** |
| Definition, scope, checklist, Scientifically sound study hypotheses, influence on design, intention to treat, subgroup analysis, interim analysis, scientific misconduct, description of access control, publication policy. | |
| **Unit-6 Strategy of clinical trial design 5 hours** | |
| Types of control groups including no control, placebo control, and active control, concomitant treatment, various way of randomization, various way of bias, blinding (open label, single blind, double blind, triple blind). | |

**Suggested Readings**

5. Guide to Clinical Trials (Volume-I &II), DCGI
6. Modules of Clinical trial methodology and management, RHE Life Science (CRO)
7. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ
8. 2. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)

| **Name of The Course** | **Medical Writing** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT5006** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:

3) Creating documents for medical records & reference retrieval
4) To understand the different aspects of medical writing

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Importance of Medical Writing in Clinical Trial, Letter writing for editorial process, Reviewing, editing and publishing |
| CO2 | Writing Article, Research report and paper writing, systematic review |
| CO3 | Software for medical writing, Literature search and Pubmed search, Meta analysis |
| CO4 | Documents in Clinical Research, Designing and development of clinical research documents |
| CO5 | Guidelines for medical writing, Guidelines and Checklists of relevant to medical writing in diverse medical fraternities |
| CO6 | Analyze the Development of medical writing in India |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Introduction to Medical Writing 7 hours** |
|---|
| Introduction, exercises and examples, Good Publication Practices, Overview of scientific articles, Reviews, Research and submission, journal and selection, Letter writing for editorial process |
| **Unit-2: Fundamentals of Manuscript 7 hours** |
| Basic introduction to medical terminology and fundamentals of medical writing, Literature survey-Use of books and journals and internet, Research report and paper writing, systematic review, Patient narrative preparation |
| **Unit-3: Software application in medical writing 7 hours** |
| Introduction to Software, Objective, Scope, article writing and plagiarism software, Literature search and search engine, analytical tools |
| **Unit-4 : Documentation and Development 7 hours** |
| Clinical study report, Designing and development of clinical research documents i.e. protocol, ICF, CRF, SOP on various functional clinical trial procedures, Pharmacovigilance writing: ICSR, SAE reporting, Narratives, PSUR, DSUR, etc. |
| **Unit-5: Guidelines 7 hours** |
| Duties of Author and disputes, Publication policy, Editor, Reviewer, Common technical document (CTD), dossier writing, ICMJE and other bodies, Checklists, Ethical consideration, Journal quality and impact assessment and Citation |
| **Unit-6: Development of medical writing in India 5 hours** |
| The history of medical writing in India; medical writing in India—the current scenario; challenges in medical writing and possible solutions |

**Suggested Readings**:


7. Guidelines for Reporting Health Research by David Moher Doughlas Altman BMJ books; August 2014
8. Medical Writing: A Guide for Clinicians, Educators, and Researchers Second Edition; Springer 2011
9. Medical writing a good practice guide by Justina-Orleans;WileyBlackwell 2012
10. Asher R. How to present your article. BMJ, 2: 502, 1958.
11. Stephen Lock Thornes's better medical writing, Pitmen Medical, 2nd Ed. 6. 1977.
12. Fraser HS. Writing a scientific paper. West Indian Med J; 44 (4): 114-24, 1995.
13. Bradford Hill A. Logical order for a scientific paper. BMJ; 2: 870, 1965.
14. Gustavii B. How to write and illustrate a scientific paper. Cambridge Univ P.BMA 2003.
15. Hall GM. How to write a paper. BMJ Books. BMA 2003.

| Name of The Course | Genomics & Proteomics | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT5007** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:
Students will get exposure about basic fundamental concepts of Genomics & Proteomics

**Course Outcomes**:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Introduction to Genomics |
| CO2 | Understand about the Genome sequencing |
| CO3 | Understand about the DNA Microarray technology |
| CO4 | Understand about the Proteomics |
| CO5 | Understand about the Tools and techniques of Genomics |
| CO6 | Analyze the Tools and techniques of Proteomics |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Introduction to Genomics** | **7 hours** |
|---|---|
| Structure and organization of prokaryotic and eukaryotic genomes - nuclear, mitochondrial and chloroplast genomes; Computational analysis of sequences- finding genes and regulatory regions; Gene annotation; Similarity searches; Pairwise and multiple alignments; Alignment statistics; Prediction of gene function using homology, context, structures, networks; Genetic variation-polymorphism, deleterious mutation; Phylogenetics; Tools for genome analysis– PCR, RFLP, DNA fingerprinting, RAPD, Automated DNA sequencing; Linkage and pedigree analysis; Construction of genetic maps; Physical maps, FISH to identify chromosome landmarks | |

| **Unit-2: Genome sequencing** | **7 hours** |
|---|---|
| Human genome project-landmarks on chromosomes generated by various mapping methods; BAC libraries and shotgun libraries preparation; Physical map-cytogenetic map, contig map, restriction map, DNA sequence; DNA sequencing and sequence assembly; Model organisms and other genome projects; Comparative genomics of relevant organisms such as pathogens and non-pathogens; Evolution of a pathogen e.g. Hepatitis C virus or a bacterial pathogen; Taxonomic classification of organisms using molecular markers- 16S rRNA typing/sequencing | |

| **Unit-3: DNA Microarray technology** | **7 hours** |
|---|---|
| Basic principles and design: cDNA and oligonucleotide arrays; Applications: Global gene expression analysis, Comparative transcriptomics, Differential gene expression; Genotyping/SNP detection; Detection technology; Computational analysis of microarray data | |

| **Unit-4: Proteomics** | **7 hours** |
|---|---|
| Overview of protein structure-primary, secondary, tertiary and quarternary structure; Relationship between protein structure and function; Outline of a typical proteomics experiment; Identification and analysis of proteins by 2D analysis; Spot visualization and picking; Tryptic digestion of protein and peptide fingerprinting; Mass spectrometry : ion source (MALDI, spray sources); analyzer (ToF, quadrupole, quadrupole ion trap) and detector; clinical proteomics and disease biomarkers; Prions; proteins in disease; Protein-protein interactions: Solid phase ELISA, pull-down assays (using GST-tagged protein), far western analysis, by surface plasmon resonance technique, Yeast two hybrid system, Phage display; Protein interaction maps; Protein arrays-definition, applications- diagnostics, expression profiling | |

| **Unit-5: Tools and techniques of Genomics** | **7 hours** |
|---|---|
| Human disease genes; DNA polymorphism including those involved in disease; Hemoglobin and the anemias; Phenylketonuria (monogenic) and diabetes (multigenic) genetic disorders; ‘disease’ gene vs. ‘susceptibility’ gene; SNP detection: hybridization based assays (allele specific probes); Polymerization based assays | |

| |
|---|
| (allele specific nucleotide incorporation, allele-specific PCR); Ligation based assays (allele specific oligonucleotide ligation); Polymorphism detection without sequence information: SSCP; |
| **Unit-6: Tools and techniques of Proteomics 5 hours** |
| Proteomics and drug discovery; High throughput screening for drug discovery; Identification of drug targets; Pharmacogenomics and pharamacogenetics and drug development; Toxicogenomics; Metagenomics |

**Suggested Readings:**


1. Brown TA, Genomes, 3rd Edition, Garland Science, 2006
2. Campbell AM & Heyer LJ, Discovering Genomics, Proteomics and
3. Bioinformatics, 2nd Edition, Benjamin Cummings, 2007.
4. Primrose S & Twyman R, Principles of Gene Manipulation and Genomics, 7th Edition, Blackwell, 2006.


| **Name of The Course** | **Electrophysiology** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBT5008** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:

To impart the complete knowledge of Electrophysiology which forms the base of Bioinstrumentation i.e. how Bioelectric signals are generated, propagated, transduced, amplified and recorded. Proper recording of the bioelectric signals help in diagnosis of the diseases.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Understanding of bioelectric phenomena |
| CO2 | Understanding of Interaction of signals |
| CO3 | Understanding of Electrical circuit model of the membrane |
| CO4 | Analyze the ECG EMG and EEG |
| CO5 | Examine the Central nervous system and neuro-control mechanisms |
| CO6 | Analyze the Receptors as biological transducers |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| |
|---|
| Unit-1: **Introduction to bioelectric phenomena 7 hours** |
| Bioelectric phenomena, Neurons and Synapse; Generation, Transmission and Propagation of signals in nervous systems – Resting Potential, Action Potential, Synaptic Potential. |
| Unit-2: **Interaction of signals 7 hours** |
| EPSP (Excitatory Post Synaptic Potentials) and IPSP (Inhibitory Post Synaptic Potentials); Interaction of signals to control various functions and reflexes of body. |
| Unit-3: **Electrical circuit model of the membrane 7 hours** |
| Electrical circuit model of the bio-membrane, The Laws of stimulation and conduction of nerve impulse. |
| Unit-4 : **ECG EMG and EEG 7 hours** |
| Electrocardiography (ECG) and its diagnostic applications– Generation and propagation of cardiac impulse, SA node as Pacemaker, Ectopic Pacemakers, PQRST Wave Pattern. Various cardiographic leads (Limb leads, Chest leads), Vectorial analysis of normal and diseased heart Electrophysiological signals- EMG, Brain potentials and their generation, Propagation, recording and diagnostic applications. |
| Unit-5: **Central nervous system and neuro-control mechanisms 7 hours** |
| Nervous system, Neuro-Anatomy in brief, Neural circuits for processing information, Central Nervous System, Peripheral Nervous System, Ventricle and Cerebrospinal Fluid, Neuro control Mechanisms |
| **Unit-6 Receptors as biological transducers 5 hours** |
| Receptors as biological transducers, Transduction and Amplification in receptors, Properties of receptors. |

**Suggested Readings**:

7. Introduction to Neurobiophysics, Vasilescu, S.G. Margineanu, Abascus Press, Tunbridge Wells, Vent.
8. Text Book of Medical Physiology, Guyton A.C. and J.E. Hall, Harcourt India Pvt. Ltd.
9. Anatomy and Physiology, Ross and Wilson, Churchill Livingstone.

| **Name of The Course** | **Project work** | | | |
|---|---|---|---|---|
| **Course Code** | **BMBP5051** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | **0** | **0** | **34** | **17** |

**Course Objectives:**
Students will get exposure of Project work execution in the area of Medical Biotechnology.

Course Outcomes

**On completion of this course the students will be able to**

| | |
|---|---|
| CO1 | Formulate questions and to discover feasible solutions |
| CO2 | Demonstrate individual initiative or group responsibility |
| CO3 | Use resource materials to express ideas and talents |
| CO4 | Design and execute the project work |
| CO5 | Report the project work in terms of thesis |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **60** | **00** | **240** | **300** |

**Course Content**

| Unit-1: **Medical Biotechnology Project work** |
|---|
| Six components are required for project completion: 1.Self-Management component 3. Written component 3. Research component 4. Oral component 5. Technological component 6. Visual component |

This project work is to make the student acquainted with the Medical Biotechnology sectors/Healthcare sector/ industrial/Medical Diagnosis and Therapeutics. After completion of the project they will have to submit dissertation report.

This project work or thesis presents a student's research results, describing the research with reference to relevant work done as part of the live project at a Hospital/Healthcare sector/ Medical Biotechnology sectors with specific diseases, diagnosis and therapeutic or rehabilitation engineering. It will include a description of the methods of research considered, and those actually employed, and present the student's conclusions. The thesis is the student's own work and must be written by the student.

The Internal Layout of the project work or Thesis

The thesis is to be submitted in the following pattern,

- Title page;
- Declarations and Statements
- Author's declaration
- Acknowledgement
- Contents page;
- Table of contents
- List of tables
- List of figures
- Definitions or Abbreviations
- Summary (Abstract)
- Introduction
- Literature Review
- Materials and Methods
- Results & Discussion
- Conclusion and Future Prospectives
- List of references
- Index

GALGOTIAS UNIVERSITY

(Established under Galgotias University Uttar Pradesh Act No. 14 of 2011)

# Program: M.Sc. Medical Biotechnology

**Scheme: 2020-2021**

**Vision: To be known globally for education, innovation and interdisciplinary research in Biosciences, Healthcare and Biomedical Engineering**.

**Mission:**

**M1**. To establish the centre of excellence in medical biotechnology.

**M2**. To establish state-of-the-art facilities of medical biotechnology for world class education and research.

**M3**. To conduct the multidisciplinary research in collaboration with national and international organization for developing the innovative solutions of unsolved health problems.

**M4**. To develop medical biotech leaders having regulatory and ethical mindset with capability of creating value in healthcare organization.

**Program Educational Objectives:**

**PEO** 1. Graduates shall conduct the research in biotechnology, healthcare, biomedical science and interdisciplinary field efficiently and ethically.

**PEO** 2. Graduates of medical biotechnology shall excel in higher studies and interdisciplinary research exhibiting global competitiveness.

**PEO** 3. Graduates have a high sense of medical responsibilities and ethical thinking and solve new/unsolved/unmet medical need

**Program Specific Objectives:**

**PSO**1. Evaluate critical domestic and global regulatory and health care issues that challenge and influence biomedical and biotech product development

**PSO**2. Demonstrate competencies in performing the biotech research; evaluating, analysing and presenting the biotech research results.

**PSO**3. Effectively communicate and collaborate with biotech service providers and regulatory agencies to develop culturally diverse domestic and global strategies for medical biotechnology.

**PSO**4. Demonstrate regulations, social and ethical values required to make a global biotech research professional

**Program Outcomes:**

**PO1- Medical Biotechnology Knowledge**: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of Medical Biotechnology, including Human Physiology, Bioinstrumentation, Biosafety, Pharmacology and Toxicology, Microbial Technology, Drug Development, Genetic Engineering, Immunotechnology, Medicinal chemistry, Animal Biotechnology, Biomaterials & Tissue Engineering, Industrial Bioprocess Technology, and Molecular Diagnostics & Therapeutics.

**PO2- Planning Abilities**: Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

**PO3- Problem analysis**: Utilize the principles of Analytical thinking, clearly and critically, while solving problems and making decisions during research design. Find, analyse, evaluate and apply information systematically and making decisions related to Medical Biotechnology.

**PO4- Modern tool usage**: Learn and apply modern and appropriate tools related to Medical Biotechnology. As example, Drug Designing, Statistical Analytical System (SAS), Molecular Diagnostics & Therapeutics, Immunotechnology, and Industrial Bioprocess Technology.

**PO5- Leadership skills**: Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfilment of practice, professional and societal responsibilities.

**PO6- Professional Identity**: Understand, analyse and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, Medical Biotechnologist, managers, employers, employees)

**PO7- Medical Biotechnology Ethics**: Honour human values and apply ethical principles in research, professional and social contexts. Demonstrate behaviour that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions during the conduction of studies related to Medical Biotechnology.

**PO8- Communication**: Communicate effectively with the Medical & Healthcare community.

**PO9- The Medical Biotechnology and society**: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the Medical Biotechnology practices.

**PO10- Environment and sustainability**: Understand the impact of the Medical Biotechnology solution in societal and environmental contexts, demonstrate the knowledge of, and need for Bio Waste Management.

**PO11- Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-access and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

## Curriculum

| Semester 1 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sl. No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | MMBT1001 | Research Methodology and Biostatistics | 4 | 0 | 0 | 4 | 20 | 30 | 50 |
| 2 | MMBT1002 | Medical Physiology-I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | MMBT1003 | Medical Microbiology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | | Disruptive technologies | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 5 | | Professional communication | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | | Environmental Studies | 0 | 0 | **1** | 0.5 | 50 | -- | 50 |
| 7 | | Campus to corporate | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 8 | | Ethics and Professional Competency | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 9 | | Creative / Liberal Arts | 0 | 0 | **1** | 0.5 | 50 | -- | 50 |
| 10 | | Waste management | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 11 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **21** | **0** | **2** | **22** | **280** | **270** | **550** |
| **Semester II** | | | | | | | | | |
| Sl No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | MMBT2001 | Analytical Techniques | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | MMBT2002 | Genetic Engineering | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | MMBT2003 | Medical Physiology-II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | MMBT2004 | Molecular Diagnostics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | Open Elective | Elective-I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | MMBP2051 | Medical Biotechnology Lab -I | 0 | 0 | **4** | 2 | 50 | -- | 50 |
| 7 | | Professional communication | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 8 | | Foreign Language | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 9 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **21** | **0** | **4** | **23** | **210** | **240** | **450** |
| **Semester III** | | | | | | | | | |
| Sl No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | MMBT3001 | Drug Discovery and Development | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | MMBT3002 | Molecular Therapeutics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | MMBT3003 | Nanobiotechnology and Biosensors | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | Open Elective | Elective-II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | MMBP3051 | Medical Biotechnology Lab -II | 0 | 0 | **4** | 2 | 50 | -- | 50 |
| 6 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 7 | | Disaster Management | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 8 | | AI and its application | 0 | 0 | **4** | 2 | 50 | -- | 50 |
| 9 | | Creativity, Innovation and entreperneurship and IPR | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **16** | **0** | **8** | **20** | **240** | **210** | **450** |
| **Semester IV** | | | | | | | | | |
| Sl No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | MMBP4051 | Project Work | 0 | 0 | 30 | 15 | 60 | -- | 240 |
| | | **Total** | **0** | **0** | 30 | 15 | 60 | -- | 240 |

## List of Electives

**Elective-1**

| Sl No | Course Code | Name of the Electives | | | | | Assessment Pattern | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | MMBT2005 | Clinical Research Overview | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | MMBT2006 | Pharmacogenomics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | MMBT2007 | Designing Clinical Trials | 3 | 0 | 0 | 3 | 20 | 30 | 50 |

**Elective-2**

| Sl No | Course Code | Name of the Elective | | | | | Assessment Pattern | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | MMBT3004 | Genomics & Proteomics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | MMBT3005 | Regulatory affairs and Ethics in Clinical Research | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | MMBT3006 | Electrophysiology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |

# Semester I

| Name of The Course | **Research Methodology & Biostatistics** | | | |
|---|---|---|---|---|
| Course Code | **MMBT1001** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 4 | 0 | 0 | 4 |

**Course Objectives:**
Students will get exposure about Research Methodology

**Course Outcomes:**
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Research |
| CO2 | Understand about the Research Design |
| CO3 | Understand about the Research Report and ethics |
| CO4 | Understand about the Sampling methods |
| CO5 | Understand about the Measures of central tendency |
| CO6 | Understand about Hypothesis testing |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Introduction to Research** | 8 hours |
|---|---|
| Research definition, types, advantage and significance. Introduction to research methods, identifying research problem, definition, objectives, role, scope in biotech research, process of research, limitations & types | |
| **Unit-2: Research Design** | 7 hours |
| Concept of Interdisciplinary Research, Procedures in research. Types of Research Design: Experimental/Interventional research, Quasi-experimental studies, Observational research. Sources of Experimental Errors. Survey research: Types of surveys- CATI, CAPI, Mail, Email, Face-to-face, Questionnaire | |
| **Unit-3: Research Report and ethics** | 5 hours |
| Type of research report- Research, review, case report, manuscript, monograph, book chapters. Structure of Research Reports. Quoting of reference and bibliography using reference management tools. Ethical issues in research, plagiarism. | |
| **Unit-4: Sampling methods** | 5 hours |
| Sampling methods, Advantages and Limitation, Sampling process, Types of Sampling, Probability and Non Probability sampling techniques, sampling errors, Data collection Primary and secondary data, Collection and validation. | |
| **Unit-5: Measures of central tendency** | 8 hours |
| Measures of central tendency- Mean, Median, Mode; Measures of dispersion- Range, Mean deviation and Coefficient of variation, Standard deviation, Standard error; Correlation and regression; Statistical inference- Hypothesis testing, Significance level, Confidence interval, t-test, z-test. Test of significance for large and small samples; Parametric tests; Non parametric tests; Experimental design, Use of biostatistic softwares. | |
| **Unit-6: Hypothesis testing** | 7 hours |
| Null hypothesis and test of significance (t-test, paired t-test, Analysis of variance, Analysis of covariance, Coefficient of Variation, chi-square test, Fischer exact, Mann-Whitney, Wilcoxin, McNeman test, Kruskal Wallis. | |

**Suggested Readings:**


1. Graziano AM, Raulin ML. Research methods: A process of inquiry. HarperCollins College Publishers; 1993.
2. C.R. Kothari : Research Methodology, New Age International Publishers
3. Bouma GD, Ling R, Wilkinson L. The research process. Oxford: Oxford University Press; 1993 Mar 30.
4. Dawson B, Trapp RG. Basic and clinical biostatistics. Singapore. 2004;2001:141-2.


| Name of The Course | **Medical Physiology-I** | | | |
|---|---|---|---|---|
| Course Code | **MMBT1002** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

Students will understand about the human physiology including muscle, cardiac, endocrine and nervous systems.

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the basic concepts of physiology and Homeostasis |
| CO2 | Understand the muscle physiology. |
| CO3 | Understand the cardiac physiology |
| CO4 | Understand the endocrine physiology |
| CO5 | Understand about the nervous system physiology. |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| Unit-1: **Introduction to Physiology** | 8 hours |
|---|---|
| Introduction to Physiology: Definition of physiology; Relationship between structure and function Levels of Organization in the Body: Cells as the basic units of life; Organizational levels of tissues, organs, systems, and organism; Concept of Homeostasis: Significance of the internal environment, Necessity of homeostasis; Factors that are homeostatically maintained, Contributions of each body system to homeostasis; Homeostatic Control Systems: Components of a homeostatic control system, Negative and positive feedback; feed forward mechanisms | |
| Unit-2: **Muscle Physiology** | 8 hours |
| Structure of Skeletal Muscle: Levels of organization in muscle, Thick- and thin-filament composition; Molecular Basis of Skeletal Muscle Contraction: Sliding filament mechanism, Excitation–contraction coupling, Skeletal Muscle Mechanics, Skeletal Muscle Metabolism and Fiber Types; Control of Motor Movement | |
| Unit-3: **Cardiac Physiology** | 8 hours |
| Anatomy of the Heart; Electrical Activity of the Heart; Mechanical Events of the Cardiac Cycle; Cardiac Output and Its Control; Nourishing the Heart Muscle; Blood Pressure: Factors influencing mean arterial pressure; Baroreceptor reflex; Blood; Plasma: Hematocrit, Composition and functions of plasma, Plasma proteins, Blood cells | |
| Unit-4: **Endocrine system** | 8 hours |
| General Principles of Endocrinology; Hypothalamus and Pituitary; Endocrine Control of Growth; Pineal Gland and Circadian Rhythms; Thyroid Gland; Adrenal Glands | |
| Unit-5: **Nervous System** | 8 hours |
| Introduction to Neural Communication, Graded Potentials, Action Potentials, Synapses and Neuronal Integration, Introduction to Hormonal Communication, Organization and Cells of the Nervous System Central nervous system; peripheral nervous system, The three classes of neurons, Glial cells, Protection and Nourishment of the Brain, Spinal Cord | |

**Suggested Readings:**


1. Sherwood, L., 2010. Human Physiology: From Cell to System. Seventh Editions. Brooks/Cole, Cengage Learning

2. Textbook of Medical Physiology 10th Ed. By Arthur C. Guyton and John E. Hall, Harcourt Asia Pte Ltd.
3. Essential Medical Physiology 3rd Ed By Leonard R. Johnson, Elsevier Academic Press.
4. Principles of Anatomy and Physiology 10th Edition By Gerard J. Tortora and Sandra Grabowski. Publisher: John Wiley and Sons.
5. Principles of Human Physiology (Paperback) By Cindy L. Stanfield and William J. Germann. Publisher: Pearson Education.
6. Samson Wright's Applied Physiology 13th Ed. CA Keele, E Neil & N Joels. Oxford University Press

| Name of The Course | **Medical Microbiology** | | | |
|---|---|---|---|---|
| Course Code | **MMBT1003** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

Students will understand about the medical microbiology.

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Infections of the Gastrointestinal Tract |
| CO2 | Understand the Infections of the Respiratory system. |
| CO3 | Understand the Pyrexial Illness |
| CO4 | Understand the Infections of the Nervous System |
| CO5 | Understand about the Sexually Transmitted Diseases and Congenital Infections. |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| Unit-1: **Infections of the Gastrointestinal Tract** | 8 hours |
|---|---|
| Amoebiasis; Giardiasis and cryptosporidiosis; Intestinal infection by nematodes; Intestinal infection by cestodes (taeniasis and H.nana infection); Trematodes; Bacterial food poisoning(toxic and infective); *E.coli* Diarrhoea; Cholera; Bacillary dysentery; Hepatitis | |
| Unit-2: **Infections of the Respiratory system** | 8 hours |
| Streptococcal infections; Viral infections; Diphtheria; Whooping cough; Bacterial pneumonias (Haemophilus and GNB, Pneumococcus/Legionella/ etc); Tuberculosis | |
| Unit-3: **Pyrexial Illness** | 8 hours |
| Malaria; Kala-azar; Leishmaniasis; Filaria; Enteric fever; Brucellosis; Rickettsial diseases; Leptospirosis and relapsing fever; Viral Hemorragic fever | |
| Unit-4: **Infections of the Nervous System** | 8 hours |
| Viral encephalitis and Aseptic meningitis; Rabies; Cysticercosis and other CNS parasitic infections; Tetanus | |
| Unit-5: **Sexually Transmitted Diseases and Congenital Infections** | 8 hours |
| Herpes Simplex virus infections; HIV infection and AIDS; Chlamydial infection; Syphilis; Mycoplasma and Ureaplasma infection; Gonorrhea and other bacterial STD; Congenital viral infections; Toxoplasmosis | |

**Suggested Readings:**

1. Prescott, L.M., Harley, J.P. and Klein, D.A. (1999) Microbiology. W.C.B.Oxford.
2. Topley and Wilson's Microbiology and Microbial Infections by Leslie Collier Edward Arnold 9th edition
3. Heritage, J., Evance, E.G.V. and Killington, R.A. (1999) Microbiology in action. Cambridge University Press.
4. Betty Forbes, Daniel Sahm, Alice Weinfield, Bailey-Scott's Diagnostic Microbiology, 12th Edition, Mosby. 2007.
5. Gerald Collee J, Andrew G Fraser, Barrie P Marmion, Mackie and McCartney's Practical Medical Microbiology, Elsevier. 2006.
6. Elmer W Koneman et al., Koneman's, Color Atlas and Text Book of Diagnostic Microbiology, 6th Edition, Lippincott Williams and Wilkins,2005.

## Semester II

| Name of The Course | **Analytical Techniques** | | | |
|---|---|---|---|---|
| Course Code | **MMBT2001** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**
Students will understand about the Analytical Techniques used in medical Biotechnology.

**Course Outcomes:**
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic Spectroscopy Techniques |
| CO2 | Understand the Centrifugation Techniques |
| CO3 | Understand the Chromatography & Electrophoretic techniques |
| CO4 | Understand the Radioactivity techniques |
| CO5 | Understand about the Advanced Techniques |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| Unit-1: **Basic Techniques** | 8 hours |
|---|---|
| Buffers; Methods of cell disintegration; Enzyme assays and controls; Detergents and membrane proteins; Dialysis, Ultrafiltration and other membrane techniques<br>*Spectroscopy Techniques* UV, Visible and Raman Spectroscopy; Theory and application of Circular Dichroism; Fluorescence; MS, NMR, PMR, ESR and Plasma Emission spectroscopy | |
| Unit-2: **Centrifugation** | 8 hours |
| Basic principles; Mathematics & theory (RCF, Sedimentation coefficient etc); Types of centrifuge Microcentrifuge, High speed & Ultracentrifuges; Preparative centrifugation; Differential & density gradient centrifugation; Applications (Isolation of cell components); Analytical centrifugation; Determination of molecular weight by sedimentation velocity & sedimentation equilibrium methods | |
| Unit-3: **Chromatography & Electrophoretic techniques** | 8 hours |
| *Chromatography Techniques* TLC and Paper chromatography; Chromatographic methods for macromolecule separation - Gel permeation, Ion exchange, Hydrophobic, Reverse-phase and Affinity chromatography; HPLC and FPLC; Criteria of protein purity<br>*Electrophoretic techniques* Theory and application of Polyacrylamide and Agarose gel electrophoresis; Capillary electrophoresis; 2D Electrophoresis; Disc gel electrophoresis; Gradient electrophoresis; Pulsed field gel electrophoresis | |
| Unit-4: **Radioactivity** | 8 hours |
| Radioactive & stable isotopes; Pattern and rate of radioactive decay; Units of radioactivity; Measurement of radioactivity; Geiger-Muller counter; Solid & Liquid scintillation counters (Basic principle, instrumentation & technique); Brief idea of radiation dosimetry; Cerenkov radiation; Autoradiography; Measurement of stable isotopes; Falling drop method; Applications of isotopes in biochemistry; Radiotracer techniques; Distribution studies; Isotope dilution technique; Metabolic studies; Clinical application; Radioimmunoassay | |
| Unit-5: **Advanced Techniques** | 8 hours |
| Protein crystallization; Theory and methods; API-electrospray and MADI-TOF; Mass spectrometry; Enzyme and cell immobilization techniques; DNA & Peptide Synthesis. | |

**Suggested Readings:**


1. Freifelder D., Physical Biochemistry, Application to Biochemistry and Molecular Biology, 2nd Edition, W.H. Freeman & Company, San Fransisco, 1982.
2. Keith Wilson and John Walker, Principles and Techniques of Practical Biochemistry, 5th Edition, Cambridge University Press, 2000.
3. D. Holme & H. Peck, Analytical Biochemistry, 3rd Edition, Longman, 1998.
4. R. Scopes, Protein Purification - Principles & Practices, 3rd Edition, Springer Verlag, 1994.
5. Selected readings from Methods in Enzymology, Academic Press


| Name of The Course | **Genetic Engineering** |
|---|---|
| Course Code | **MMBT2002** |

| | | | | | |
|---|---|---|---|---|---|
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | **L** | **T** | **P** | **C** |
| | | **3** | **0** | **0** | **3** |

**Course Objectives:**

Students will get exposure about the tools and techniques of genetic engineering.

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of genetic engineering |
| CO2 | Understand about the Cloning Vectors |
| CO3 | Understand about the Cloning Methodologies |
| CO4 | Understand about the concepts of PCR and Its Applications |
| CO5 | Understand about the Sequencing methods and other techniques |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| Unit-1: **Basics Concepts** | 8 hours |
|---|---|
| Restriction Enzymes; DNA ligase, Klenow enzyme, T4 DNA polymerase, Polynucleotide kinase, Alkaline phosphatase; Cohesive and blunt end ligation; Linkers; Adaptors; Homopolymeric tailing; Labeling of DNA: Nick translation, Random priming, Radioactive and non-radioactive probes, Hybridization techniques: Northern, Southern and Colony hybridization, Fluorescence in situ hybridization; Chromatin Immunoprecipitation; DNA-Protein Interactions-Electromobility shift assay; DNaseI footprinting; Methyl interference assay | |
| Unit-2: **Cloning Vectors** | 8 hours |
| Plasmids; Bacteriophages; M13 mp vectors; PUC19 and Bluescript vectors, Phagemids; Lambda vectors; Insertion and Replacement vectors; EMBL; Cosmids; Artificial chromosome vectors (YACs; BACs); Animal Virus derived vectors-SV-40; vaccinia/bacculo & retroviral vectors; Expression vectors; pMal; GST; pETbased vectors; Protein purification; His-tag; GST-tag; MBP-tag etc.; Intein-based vectors; Inclusion bodies; Methodologies to reduce formation of inclusion bodies; Baculovirus and pichia vectors system, Plant based vectors, Ti and Ri as vectors, Yeast vectors, Shuttle vectors | |
| Unit-3: **Cloning Methodologies** | 8 hours |
| Insertion of Foreign DNA into Host Cells; Transformation; Construction of libraries; Isolation of mRNA and total RNA; cDNA and genomic libraries; cDNA and genomic cloning; Expression cloning; Jumping and hopping libraries; Southwestern and Far-western cloning; Protein-protein interactive cloning and Yeast two hybrid system; Phage display; Principles in maximizing gene expression | |
| Unit-4: **PCR and Its Applications** | 8 hours |
| Primer design; Fidelity of thermostable enzymes; DNA polymerases; Types of PCR – multiplex, nested, reverse transcriptase, real time PCR, touchdown PCR, hot start PCR, colony PCR, cloning of PCR products; Tvectors; Proof reading enzymes; PCR in gene recombination; Deletion; addition; Overlap extension; and SOEing; Site specific mutagenesis; PCR in molecular diagnostics; Viral and bacterial detection; PCR based mutagenesis, Mutation detection: SSCP, DGGE, RFLP, Oligo Ligation Assay (OLA), MCC (Mismatch Chemical Cleavage, ASA (Allele-Specific Amplification), PTT (Protein Truncation Test) | |
| Unit-5: **Sequencing methods and other techniques** | 8 hours |
| Sequencing methods; Enzymatic DNA sequencing; Chemical sequencing of DNA; Automated DNA sequencing; RNA sequencing; Chemical Synthesis of oligonucleotides; Introduction of DNA into mammalian cells; Transfection techniques; Gene silencing techniques; Introduction to siRNA; siRNA technology; Micro RNA; Construction of siRNA vectors; Principle and application of gene silencing; Gene knockouts and Gene Therapy; Creation of knockout mice; Disease model; Somatic and germ-line therapy- in vivo and ex-vivo; Suicide gene therapy; Gene replacement; Gene targeting; Transgenics; cDNA and intragenic arrays; Differential gene expression and protein array. | |

**Suggested Readings**


1. S.B. Primrose, R.M. Twyman and R.W.Old; Principles of Gene Manipulation. 6th Edition, S.B.University Press, 2001.
2. J. Sambrook and D.W. Russel; Molecular Cloning: A Laboratory Manual, Vols 1-3, CSHL, 2001.

3. Brown TA, Genomes, 3rd ed. Garland Science 2006
4. Nicholl DS. An introduction to genetic engineering. Cambridge University Press; 2008 May 29.
5. Glick BR, Patten CL. Molecular biotechnology: principles and applications of recombinant DNA. John Wiley & Sons; 2017 Jun 1

| Name of The Course | **Medical Physiology-II** | | | |
|---|---|---|---|---|
| Course Code | **MMBT2003** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**
Students will understand about the human physiology including respiratory, urinary, digestive, integumentary, special senses and reproductive systems.

**Course Outcomes:**
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the concepts of respiratory system. |
| CO2 | Understand the concepts of urinary system |
| CO3 | Understand the concepts of digestive system |
| CO4 | Understand the concepts of special senses & integumentary system |
| CO5 | Understand about the concepts of reproductive system. |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**:

| **Unit-1: The Respiratory System** | 8 hours |
|---|---|
| Respiratory Anatomy; Respiratory Mechanics; Gas Exchange; Gas transport; Control of Respiration | |
| **Unit-2**: **The Urinary System** | 8 hours |
| Kidneys: Functions, Anatomy, and Basic Processes; Glomerular Filtration; Tubular Reabsorption; Tubular Secretion; Urine Excretion and Plasma Clearance; Excretion of urine of varying concentrations; medullary countercurrent system Vasopressin-controlled H2O reabsorption Renal failure; Micturition | |
| **Unit-3**: **The Digestive System** | 8 hours |
| General Aspects of Digestion; Mouth; Pharynx and Esophagus; Stomach; Pancreatic and Biliary Secretions; Small Intestine; Large Intestine; Overview of the Gastrointestinal Hormones | |
| **Unit-4**: **Integumentary system & Special Senses** | 8 hours |
| Skin, Receptor Physiology; Pain; Eye: Vision; Ear: Hearing and Equilibrium; Chemical Senses: Taste and Smell | |
| **Unit-5: Reproductive System** | 8 hours |
| Uniqueness of the Reproductive System; Male Reproductive Physiology; Sexual Intercourse between Males and Females; Female Reproductive Physiology | |

**Suggested Readings**:

1. Sherwood, L., 2010. Human Physiology: From Cell to System. Seventh Editions. Brooks/Cole, Cengage Learning
2. Textbook of Medical Physiology 10th Ed. By Arthur C. Guyton and John E. Hall, Harcourt Asia Pte Ltd.
3. Essential Medical Physiology 3rd Ed By Leonard R. Johnson, Elsevier Academic Press.
4. Principles of Anatomy and Physiology 10th Edition By Gerard J. Tortora and Sandra Grabowski. Publisher: John Wiley and Sons.
5. Principles of Human Physiology (Paperback) By Cindy L. Stanfield and William J. Germann. Publisher: Pearson Education.
6. Samson Wright's Applied Physiology 13th Ed. CA Keele, E Neil & N Joels. Oxford University Press.

| Name of The Course | **Molecular Diagnostics** | | | |
|---|---|---|---|---|
| Course Code | **MMBT2004** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**
Students will understand about the tools and techniques used in the molecular diagnosis.

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the basic concepts of host pathogen interactions and Biomarkers |
| CO2 | Understand the biochemical based diagnosis. |
| CO3 | Understand the Antibodies based diagnosis |
| CO4 | Understand the DNA based diagnosis |
| CO5 | Understand about the Protein based diagnosis. |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| | |
|---|---|
| Unit-1: **Host pathogen interactions and Biomarkers** | 8 hours |
| Biomarkers- types and applications; Host pathogen interactions in disease process; Protective immune response in Bacterial, Viral and Parasitic diseases; Cancer; Inappropriate Immune response; Disease pathology and clinical spectrum; Clinical diagnosis of diseases; Molecular Genetics of the host and the pathogen | |
| Unit-2: **Biochemical based diagnosis** | 8 hours |
| Biochemical disorders; Immune, Genetic and Neurological disorders; Molecular techniques for analysis of these disorders; Assays for the Diagnosis of inherited diseases; Bioinformatic tools for molecular diagnosis | |
| Unit-3: A**ntibodies based diagnosis** | 8 hours |
| Antibody based diagnosis; Monoclonal antibodies as diagnostic reagents; Production of monoclonal antibodies with potential for diagnosis; Diagnosis of bacterial, viral and parasitic diseases by using; ELISA and Western blot. | |
| Unit-4: **DNA based diagnosis** | 8 hours |
| Isolation of DNA; purification and analysis; Aptamers; DNA sequencing and diagnosis; PCR and Array based techniques in diagnosis; Single nucleotide polymorphism and disease association; Two dimensional gene scanning | |
| Unit-5: **Protein based diagnosis** | 8 hours |
| Isolation of proteins and other molecules associated with disease; Process and their profiling for diagnosis; 2D analysis of such proteins by sequencing individual spots by Mass Spectrometry; Protein Micro array; Present methods for diagnosis of Specific diseases like Tuberculosis, Malaria and AIDS; Ethics in Molecular Diagnosis | |

**Suggested Readings:**


1. Campbell, M.A and Heyer L.J., Discovering Genomics, Proteomics and Bioinformatics, 2nd Edition, CSHL Press, Pearson/Benzamin Cummings San Francisco, USA, 2007.
2. Andrew Read and Dian Donnai, New Clinical Genetics, Scion Publishing Ltd, Oxfordshire, UK, 2007.
3. James W Goding, Monoclonal antibodies: Principles and Practice, 3rd Edition, Academic Press, 1996.
4. George Patrinos and Wilhelm Ansorage, Molecular Diagnostics, 1 st Edition, Academic Press, 2005.
5. Lela Buchingham and Maribeth L Flawsm, Molecular Diagnostics: Fundamentals, Methods and Clinical Applications, 1 st Edition, F A Davis Company, Philadelphia, USA, 2007.


## Semester III

| | | | | |
|---|---|---|---|---|
| **Name of The Course** | **Drug Discovery and Development** | | | |
| **Course Code** | M**MBT3001** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

Students will get exposure about Drug Discovery and Development

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Drug Discovery and Development |
| CO2 | Understand about the Pre-Clinical Studies |
| CO3 | Understand about the Drug designing |
| CO4 | Understand about the Methods and Process of Drug discovery |
| CO5 | Understand about the Non Clinical Drug Development |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|

| | | | |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| | |
|---|---|
| **Unit-1: Introduction to Drug development** | 8 hours |
| Need for a new Drug, Target identification, lead identification, Sources of new drugs: synthetic, natural, endogenous, peptides; compounds for screening as a potential drug, Drug Discovery & Drug development process. In vivo, in vitro and in silico studies. Animal models of diseases. | |
| **Unit-2: Pre-Clinical Studies** | 8 hours |
| Importance of Pre-Clinical studies, Steps involved in Pre-clinical studies, Types of Pre-Clinical Studies, Introduction to toxicology, Organ specific toxicity, Toxicity Studies, Bioassays; Biochemical, Molecular, Behavioural & Physiological parameter analysis , Pharmacokinetics, Pharmacology, Pharmacodynemics, Tissue distribution study | |
| **Unit-3: Drug designing** | 8 hours |
| Drug design-Ligand based, Structure based, target-centered drug design: DNA, RNA and Protein based drug designing, Structure Activity Relationship (SAR), Quantitative Structure Activity Relationship (QSAR), Computer assisted drug designing (CADD) | |
| **Unit-4: Methods and Process of Drug discovery** | 8 hours |
| High Through Put Screening (HTS): Introduction, Advantages and Disadvantages, Uses, Methodology; Combinatorial Chemistry, methods and processes; Lead optimization techniques | |
| **Unit-5: Non Clinical Drug Development** | 8 hours |
| GLP, GMP, GCP; submission of IND, NDA, ANDA | |

**Suggested Readings:**


1 Preclinical Drug Development, Edited by Mark Rogge, David R. Taft, Second Edition, 25th Sep 2009.
2 Hill RG. Drug Discovery and Development-E-Book: Technology in Transition. Elsevier Health Sciences; 2012 Jul 20.
3 Choudhary MI, Thomsen WJ. Bioassay techniques for drug development. CRC Press; 2001 Oct 4.
4 Klebe G. Drug Design: Methodology, concepts, and mode-of-action. Heidelberg, Germany: Springer; 2013 Jul 10.
5 Armstrong JD, Hubbard RE, Farrell T, Maiguashca B, editors. Structure-based drug discovery: an overview. Royal Society of Chemistry; 2006


| | | | | | |
|---|---|---|---|---|---|
| **Name of The Course** | **Molecular Therapeutics** | | | | |
| **Course Code** | **MMBT3002** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | **L** | **T** | **P** | **C** | |
| | **3** | **0** | **0** | **3** | |

**Course Objectives:**
Students will get exposure about molecular therapeutics tools and methods

**Course Outcomes:**
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Gene therapy |
| CO2 | Understand about the Cellular therapy |
| CO3 | Understand about the Recombinant therapy |
| CO4 | Understand about the Immunotherapy |
| CO5 | Understand about the Gene silencing technology |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| | |
|---|---|
| **Unit-1: Gene therapy** | 8 hours |
| Gene therapy; Intracellular barriers to gene delivery; Overview of inherited and acquired diseases for gene therapy; Retro and adeno virus mediated gene transfer; Liposome and nanoparticles mediated gene delivery | |
| **Unit-2: Cellular therapy** | 8 hours |
| Cellular therapy; Stem cells: definition, properties and potency of stem cells; Sources: embryonic and adult stem cells; Concept of tissue engineering; Role of scaffolds; Role of growth factors; Role of adult and embryonic stem cells; Clinical applications; Ethical issues | |
| **Unit-3: Recombinant therapy** | 8 hours |

| | |
|---|---|
| Recombinant therapy; Clinical applications of recombinant technology; Erythropoietin; Insulin analogs and its role in diabetes; Recombinant human growth hormone; Streptokinase and urokinase in thrombosis; Recombinant coagulation factors | |
| **Unit-4: Immunotherapy** | 8 hours |
| Immunotherapy; Monoclonal antibodies and their role in cancer; Role of recombinant interferons; Immunostimulants; Immunosupressors in organ transplants; Role of cytokine therapy in cancers; Vaccines: types, recombinant vaccines and clinical applications | |
| **Unit-5: Gene silencing technology** | 8 hours |
| Gene silencing technology; Antisense therapy; siRNA; Tissue and organ transplantation; Transgenics and their uses; Cloning; Ethical issues | |

**Suggested Readings:**


1. Bernhard Palsson and Sangeeta N Bhatia, Tissue Engineering, 2nd Edition, Prentice Hall, 2004.
2. Pamela Greenwell, Michelle McCulley, Molecular Therapeutics: 21st century medicine, 1st Edition, Springer, 2008


| **Name of The Course** | **Nanobiotechnology and Biosensors** | | | |
|---|---|---|---|---|
| **Course Code** | **MMBT3003** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**
Students will understand about the Nanobiotechnology and Biosensors.

**Course Outcomes:**
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the nanobiotechnology |
| CO2 | Understand the Biosensors |
| CO3 | Understand the Biological nanoparticles production |
| CO4 | Understand the Nanobiotechnological applications in health and disease |
| CO5 | Understand about the Nanobiotechnological applications in Environment and food |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit**-1: **Introduction to nanobiotechnology** | 8 hours |
|---|---|
| Development of nanobiotechnology - timelines and progress, overview; Nanomaterial in biotechnology - nanoparticles, quantum dots, nanotubes and nanowires | |
| **Unit-2: Biosensors** | 8 hours |
| Biosensors; different classes - molecular recognition elements, transducing elements. Applications of molecular recognition elements in nanosensing of different analytes; Application of various transducing elements as part of nanobiosensors. | |
| **Unit-3: Biological nanoparticles production** | 8 hours |
| Biological nanoparticles production - plants and microbial. Miniaturized devices in nanobiotechnology - types and applications, lab on a chip concept. | |
| **Unit-4: Nanobiotechnological applications in health and disease** | 8 hours |
| Nanobiotechnological applications in health and disease - infectious and chronic. | |
| **Unit-5: Nanobiotechnological applications in Environment and food** | 8 hours |
| Nanobiotechnological applications in Environment and food - detection and mitigation | |

**Suggested Readings**


1. Nanobiotechnology: Concepts, Applications and Perspectives (2004), Christof M.Niemeyer (Editor), Chad A. Mirkin (Editor), Wiley VCH.
2. Nanobiotechnology - II more concepts and applications. (2007) - Chad A Mirkin and Christof M. Niemeyer (Eds), Wiley VCH.


## Electives

| **Name of The Course** | **Clinical Research Overview** | | | |
|---|---|---|---|---|
| **Course Code** | **MMBT2005** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:
Students will get exposure about the need and scope of clinical research and the areas of clinical research. They will learn about different phases of clinical research.

**Course Outcomes**:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the basic concepts of Clinical Research. |
| CO2 | Understand the historical perspective of clinical research |
| CO3 | Understand the different phases and types of clinical Trials |
| CO4 | Understand the concepts of IPR with major emphasis on patents |
| CO5 | Understand about the bioequivalence and bioavailability (BA/BE) studies |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| **Unit-1: Introduction to Clinical Research** | 8 hours |
|---|---|
| Definition of Clinical research, Terminologies & definitions used in Clinical Research, Difference between Clinical Research and Clinical practice, Glossary of GCP. Historical Aspects of clinical research, Brief description of different phases, Stakeholders in clinical research, Need and scope of clinical research, Areas of clinical research, career opportunities in clinical research | |
| **Unit-2: The Historical Prospective of Clinical Research** | 8 hours |
| A Brief History of Clinical Research, Sulphanilamide Tragedy, Thalidomide Disaster, Nazi Experiments, Tuskegee Study, Belmont Report, Nuremberg Code, Declaration of Helsinki Principles, ICH guidelines History, Structure, Process | |
| **Unit-3: Types and Phases of Clinical Trial** | 8 hours |
| Introduction to Clinical Trials – Types of Clinical Trial - Randomized trial, open label study double blind, single blind, matched pair study, cross over trial, case control study, cohort study, equivalence trials, superiority trials and non-inferiority trials<br>Phases of developmental clinical trials, Phase 0, Phase I-IV<br>Phase I –aims of phase I – selection of volunteers-informed consent-protocol –design of study;<br>Phase II- Therapeutic exploratory, objectives of phase II; Phase IIa; Phase IIb; its regulatory requirements.<br>Phase III- Therapeutics confirmatory – Objectives of phase III- design of Phase III, protocol-regulatory requirements;<br>Phase IV – purpose, types, study design for observational studies, PMS<br>Placebo response, advantage and disadvantages of Placebo | |
| **Unit-4: Pharmaceutical Industry and Globalization** | 8 hours |
| Overview, Opportunities & Career options in Clinical Research, Overview of global and local players, what are the advantages of conducting Clinical Research in India. Intellectual Property Rights: Introduction, Scope, Objectives of IPR in pharmacy, Indian legal system & its role in IPR; Concept of property with respect to intellectual creativity; Tangible & Intangible property, concept of IPR, scope & nature of patents, copyrights, trade mark, geographical limitations; Indian Patent Act 1970, Patenting in India & abroad, practical aspects of patent filing, components of a patent application in India | |
| **Unit-5: BA/BE Studies** | 8 hours |
| Bioavailability and Bioequivalence – Definition, Needs, Methods and Procedures, factors affecting Bioavailability Bioequivalence/ Therapeutic Equivalence, Study parameters: Tmax, Cmax, AUC, t1/2, Test method to assess Bioequivalence, Steady State studies, regulatory requirements, planning & design, Protocol/ CRF outline, QA & QC, Drug accountability, Elements of BE study, Facilities for conducting BA-BE study | |

**Suggested Readings**


1. Guide to Clinical Trials (Volume-I &II), ICRI
2. LachmanL, Liberman H.A and Kanig J.L., "Theory and Practice of Industrial Pharmacy", Lea and
3. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ
4. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)


| **Name of The Course** | **Pharmacogenomics** |
|---|---|
| **Course Code** | **MMBT2006** |

| | | | | | |
|---|---|---|---|---|---|
| **Prerequisite** | | | | | |
| **Corequisite** | | | | | |
| **Antirequisite** | | | | | |
| | | **L** | **T** | **P** | **C** |
| | | **3** | **0** | **0** | **3** |

**Course Objectives:**
Students will get exposure about the tools and techniques of Pharmacogenomics.

**Course Outcomes:**
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Pharmacogenomics |
| CO2 | Understand about the Polymorphisms |
| CO3 | Understand about the Drug response |
| CO4 | Understand about the concepts of Pharmacogenomic analysis |
| CO5 | Understand about the Pharmacogenomics application in clinical practice |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| | |
|---|---|
| Unit-1: Pharmacogenomics- Introduction | 8 hours |
| Pharmacogenomics- Introduction, basic concepts about genetics diseases. Personalized medicine- introduction and importance. The genetics of therapeutic targets and gene-based targets. Pharmacogenomics necessity in drug designing. Pharmacological and pharmacogenomics approaches to improve drug delivery clinical outcomes | |
| Unit-2: Polymorphisms | 8 hours |
| Polymorphisms-Introduction, types and importance in Drug targets. Prediction of structural changes among sequences by the influence of polymorphisms. Genetic polymorphism of CYP isoenzymes and drug transporters | |
| Unit-3: Drug response | 8 hours |
| Drug response to patients, Structural influence in the Drug response. Efficacy and metabolism of drugs. Pharmacogenomics vs. Structural Pharmacogenomics. Drug metabolism pathways and adverse drug reactions. | |
| Unit-4: Pharmacogenomic analysis | 8 hours |
| Tools for pharmacogenomic analysis, Process in Structural Pharmacogenomics. Personalized medicine and drug prescription, Pharmacology and pharmacogenomics of cardiovascular system, Protein drugs and the development of biotherapeutics, Development of new innovative molecularly-targeted cancer therapeutics; Cancer pharmacogenomics and biotherapeutics | |
| Unit-5: Pharmacogenomics application in clinical practice | 8 hours |
| Drugs related to the pharmacogenomics application in clinical practice: a) Pharmacodynamics- and pharmacogenomics-guided warfarin dosing in individual patients; b) Pharmacological assessment of tamoxifen-paroxetine interaction and pharmacogenomics of tamoxifen in oncology; c) Thiopurine drugs and pharmacogenomics of TPMT enzyme in guiding dosage schemes; d) Pharmacogenomics of antidepressant and psychotropic drugs; e) Pharmacogenomics of Cetuximab and Panituximab. Recombinant Coagulation Factors and Thrombolytic Agents, Recombinant Human Deoxyribonuclease I, Hematopoietic Growth Factors: Focus on Erythropoiesis-Stimulating Agents, Interferons and Interleukins | |

**Suggested Readings:**


1. Gary Walsh, Pharmaceutical Biotechnology: Concepts and Applications. John Wiley & Sons: West Sussex. 2007
2. Daan J. A. Crommelin, Robert D. Sindelar, Bernd Meibohm, Pharmaceutical Biotechnology: Fundamentals and Applications. Informa Healthcare: New York. 2008
3. J. Licinio and M.-L. Wong. Pharmacogenomics: The Search for Individualized Therapies. Wiley-Blackwell. 2009


| | | | | | |
|---|---|---|---|---|---|
| **Name of The Course** | **Designing Clinical Trials** | | | | |
| **Course Code** | **MMBT2007** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

**Course Objectives:**
Students will get exposure about the designing of clinical trial, methodology of designing and importance of designing.

**Course Outcomes:**
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of designing & development |
| CO2 | Understand about the type of designing |
| CO3 | Understand about the designing in outcomes of clinical trials |
| CO4 | Understand about the different tools used in designing |
| CO5 | Understand about the evaluation of outcome |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Introduction to clinical trial design** | 8 hours |
|---|---|
| Overview and importance of clinical trial designing, title of study, terminologies, regulatory requirement for trial design, ethical consideration to develop clinical trial design | |
| **Unit-2: Fundamentals of clinical trial design** | 8 hours |
| Objectives of clinical trial design, types of designs-observational, interventional, prospective, retrospective, single and multicentric, randomization, nonrandomization, crossover design, parallel design, comparative design, non-comparative design, single arm, multiple arm, appropriate hypotheses(superiority, inferiority, non-inferiority, equivalency). | |
| **Unit-3: Planning & strategy of clinical trial design** | 8 hours |
| Subject's recruitment, recruitment advertisement, and rule for subject withdrawal, eligibility of subject (inclusion and exclusion criteria), study procedure, recruitment period, treatment period, follow-up period, types of control groups including no control, placebo control, and active control, concomitant treatment, various way of randomization, various way of bias, blinding (open label, single blind, double blind, triple blind). | |
| **Unit-4: Efficacy and safety assessment mechanisms** | 8 hours |
| Objectives, definitions, Importance, description of efficacy methods and assessment parameters, baseline and endpoint measurements, description of safety and assessment methods, adverse event, serious adverse event, suspected adverse event, unexpected adverse event and reporting mechanisms. | |
| **Unit-5: Outcomes and analysis** | 8 hours |
| Definition, scope, checklist, Scientifically sound study hypotheses, influence on design, intention to treat, subgroup analysis, interim analysis, scientific misconduct, description of access control, publication policy. | |

**Suggested Readings**


1. Guide to Clinical Trials (Volume-I &II), DCGI
2. Modules of Clinical trial methodology and management, RHE Life Science (CRO)
3. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ
4. 2. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)


| **Name of The Course** | **Genomics & Proteomics** | | | |
|---|---|---|---|---|
| **Course Code** | **MMBT3004** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:
Students will get exposure about basic fundamental concepts of Genomics & Proteomics

**Course Outcomes**:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Introduction to Genomics |
| CO2 | Understand about the Genome sequencing |
| CO3 | Understand about the DNA Microarray technology |
| CO4 | Understand about the Proteomics |
| CO5 | Understand about the |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| Unit-1: *Introduction to Genomics* | 8 hours |
|---|---|

| | |
|---|---|
| Structure and organization of prokaryotic and eukaryotic genomes - nuclear, mitochondrial and chloroplast genomes; Computational analysis of sequences- finding genes and regulatory regions; Gene annotation; Similarity searches; Pairwise and multiple alignments; Alignment statistics; Prediction of gene function using homology, context, structures, networks; Genetic variation-polymorphism, deleterious mutation; Phylogenetics; Tools for genome analysis– PCR, RFLP, DNA fingerprinting, RAPD, Automated DNA sequencing; Linkage and pedigree analysis; Construction of genetic maps; Physical maps, FISH to identify chromosome landmarks | |
| Unit-2: *Genome sequencing* | 8 hours |
| Human genome project-landmarks on chromosomes generated by various mapping methods; BAC libraries and shotgun libraries preparation; Physical map-cytogenetic map, contig map, restriction map, DNA sequence; DNA sequencing and sequence assembly; Model organisms and other genome projects; Comparative genomics of relevant organisms such as pathogens and non-pathogens; Evolution of a pathogen e.g. Hepatitis C virus or a bacterial pathogen; Taxonomic classification of organisms using molecular markers- 16S rRNA typing/sequencing | |
| Unit-3: *DNA Microarray technology* | 8 hours |
| Basic principles and design: cDNA and oligonucleotide arrays; Applications: Global gene expression analysis, Comparative transcriptomics, Differential gene expression; Genotyping/SNP detection; Detection technology; Computational analysis of microarray data | |
| Unit-4: *Proteomics* | 8 hours |
| Overview of protein structure-primary, secondary, tertiary and quarternary structure; Relationship between protein structure and function; Outline of a typical proteomics experiment; Identification and analysis of proteins by 2D analysis; Spot visualization and picking; Tryptic digestion of protein and peptide fingerprinting; Mass spectrometry : ion source (MALDI, spray sources); analyzer (ToF, quadrupole, quadrupole ion trap) and detector; clinical proteomics and disease biomarkers; Prions; proteins in disease; Protein-protein interactions: Solid phase ELISA, pull-down assays (using GST-tagged protein), far western analysis, by surface plasmon resonance technique, Yeast two hybrid system, Phage display; Protein interaction maps; Protein arrays-definition, applications- diagnostics, expression profiling | |
| Unit-5: Tools and techniques of Genomics & Proteomics | 8 hours |
| Human disease genes; DNA polymorphism including those involved in disease; Hemoglobin and the anemias; Phenylketonuria (monogenic) and diabetes (multigenic) genetic disorders; 'disease' gene vs. 'susceptibility' gene; SNP detection: hybridization based assays (allele specific probes); Polymerization based assays (allele specific nucleotide incorporation, allele-specific PCR); Ligation based assays (allele specific oligonucleotide ligation); Polymorphism detection without sequence information: SSCP; Proteomics and drug discovery; High throughput screening for drug discovery; Identification of drug targets; Pharmacogenomics and pharamacogenetics and drug development; Toxicogenomics; Metagenomics | |

**Suggested Readings**:


1. Brown TA, Genomes, 3rd Edition, Garland Science, 2006
2. Campbell AM & Heyer LJ, Discovering Genomics, Proteomics and
3. Bioinformatics, 2nd Edition, Benjamin Cummings, 2007.
4. Primrose S & Twyman R, Principles of Gene Manipulation and Genomics, 7th Edition, Blackwell, 2006.


| **Name of The Course** | **Regulatory affairs and Ethics in Clinical Research** | | | |
|---|---|---|---|---|
| **Course Code** | **MMBT3005** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**
Students will get exposure about the ethical concepts clinical research and the process of evolution of regulatory control in clinical trial

**Course Outcomes:**
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the ethical aspects important to sound clinical research |

| | |
|---|---|
| CO2 | Understand about the IRB/IEC, Independent Ethic committees, Ethic review |
| CO3 | Understand about the operational imperatives of Good Clinical Practices |
| CO4 | Understand about the regulatory control, ICH-GCP, ICMR requirement |
| CO5 | Understand about the international regulatory bodies and guidelines |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| | |
|---|---|
| Unit-1: Ethic in clinical research | 8 hours |
| Evolution of ethic 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 a investigator, compensation to subjects/patients for clinical trial related injuries | |
| Unit-2: Overview of IRB/IEC/ERB | 8 hours |
| Independent Ethic committees, Ethic review procedures, importance of inform consent document, patient information sheet, and inform consent form, Fraud and misconduct, detection of fraud in clinical research. Ethics in academia, violation of ethic in clinical research, HIPAA | |
| Unit-3: Evolution of regulatory control | 8 hours |
| Evolution of regulatory control: An international comparison, Pure food and drug act, drug and cosmetic act 1945, thalidomide disaster, Kafauvers Harris amendment act, Waxman hatch act, Evolution of ICH, NICE. Introduction to ICH-International Conference on Harmonization of technical requirements for registration of Pharmaceuticals for human use guidelines Milestones in the evaluation of GCP | |
| Unit-4: Applicable GCP Guidelines, IND and NDA | 8 hours |
| International Conference on Harmonization of technical requirements for registration of Pharmaceuticals for human use guidelines (ICH-GCP), Indian Council Of Medical Research- Ethical Guidelines for Biomedical Research on Human participants (ICMR), Indian Good Clinical Practices IND Application :requirements forms , contents, application , Investigator IND, Treatment IND , Emergency use of IND. NDA application: contents , forms , review process, actions, Guidance documents for IND and NDA, Common Technical Document: Purpose , structure and contents | |
| Unit-5: International Regulatory bodies and Guidelines | 8 hours |
| US Food and Drug Administration(USFDA): 21CFR 50,316,314The FDA and Food Drug and Cosmetics Act, New drug development and approval : the principal steps. India: Regulatory laws, Schedule Y, registration of new drugs, requirements for registration, regulatory environment and practices, Indian GCP, CTRI<br><br>Medicines and Healthcare Products Regulatory Agency (MHRA): Overview of regulatory environment/ background, regulatory authorities, regulatory requirements and procedures. European Agency for Evaluation of medicinal Products(EMEA): National registration , the decentralized procedures, mutual recognition procedures. Brazil: Overview of regulatory affairs | |

**Suggested Readings**:

1. Guide to Clinical Trials (Volume-I &II), ICRI
2. Good Clinical Practice by Josef Kolman, Paul Meng
3. Guideline for Drug Regulatory Submissions by Sandy Welnberg
4. International Pharmaceutical Registration by Alan A Chalmers

| **Name of The Course** | **Electrophysiology** | | | |
|---|---|---|---|---|
| **Course Code** | **MMBT3006** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**

To impart the complete knowledge of Electrophysiology which forms the base of Bioinstrumentation i.e. how Bioelectric signals are

generated, propagated, transduced, amplified and recorded. Proper recording of the bioelectric signals help in diagnosis of the diseases.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Understanding of bioelectric phenomena |
| CO2 | Analysing the Interaction of signals & Receptors |
| CO3 | Examine the Electrical circuit model of the membrane |
| CO4 | Understanding of ECG EMG and EEG |
| CO5 | Analysing of Central nervous system and neuro-control mechanisms |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| |
|---|
| Unit-1: Introduction to bioelectric phenomena 9 hours |
| Generation, transmission and propagation of signals in nervous systems- Resting Potential, Action Potentials. Synapse, Synaptic Potentials-EPSP (Excitatory Post Synaptic Potentials) and IPSP (Inhibitory Post Synaptic Potentials) Interactions of signals |
| Unit-2: Interaction of signals & Receptors 9 hours |
| Discussion of initiation and propagation of action potential along nerve fibers. Compound Action Potentials. Receptors as Biological Transducers, Transduction and Amplification in Receptors<br>Properties of receptors |
| Unit-3: Electrical circuit model of the membrane 9 hours |
| Electrical circuit models of the Bio-membrane Frequency modulation of the electrical signals. Voltage clamp experiments. |
| Unit-4 : ECG EMG and EEG 9 hours |
| Electrocardiography (ECG) and its diagnostic applications– Generation and propagation of cardiac impulse, SA node as Pacemaker, Ectopic Pacemakers, PQRST Wave Pattern. Various cardiographic leads (Limb leads, Chest leads), Vectorial analysis of normal and diseased heart. Electromyography signals-EMG, its diagnostic applications |
| Unit-5: Central nervous system and neuro-control mechanisms 9 hours |
| Brain Potentials and their generation, recording and diagnostic applications. Neural control mechanism |

**Suggested Readings:**


1. Introduction to Neurobiophysics, Vasilescu, S.G. Margineanu, Abascus Press, Tunbridge Wells, Vent.
2. Text Book of Medical Physiology, Guyton A.C. and J.E. Hall, Harcourt India Pvt. Ltd.
3. Anatomy and Physiology, Ross and Wilson, Churchill Livingstone.


| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | Project Work | | | | |
| Course Code | MMBP4051 | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 0 | 0 | 30 | 15 |

**Course Objectives:**

Students will get exposure of Project work execution in the area of Medical Biotechnology.

Course Outcomes

**On completion of this course the students will be able to**

| | |
|---|---|
| CO1 | Formulate questions and to discover feasible solutions |
| CO2 | Demonstrate individual initiative or group responsibility |
| CO3 | Use resource materials to express ideas and talents |
| CO4 | Design and execute the project work |
| CO5 | Report the project work in terms of thesis |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|

| | | | |
|---|---|---|---|
| **60** | **00** | **240** | **300** |

**Course Content**

| |
|---|
| Unit-1: Clinical trial Project<br>9 hours |
| Six components are required for project completion: 1.Self-Management component |

4. Written component 3. Research component 4. Oral component 5. Technological component 6. Visual component

GALGOTIAS UNIVERSITY

(Established under Galgotias University Uttar Pradesh Act No. 14 of 2011)

# Program: B.Sc Nutrition and Dietetics

**Scheme: 2020-2021**

**Vision:-** To be known globally for education, innovation and interdisciplinary research in Biosciences, Healthcare and Biomedical Engineering.

**Mission:**

**M1**. To establish the centre of excellence in Nutrition and Dietetics.

**M2**. To establish state-of-the-art facilities of Nutrition and Dietetics for world class education and research.

**M3**. To conduct the multidisciplinary research in collaboration with national and international organization for developing the innovative solutions of unsolved health problems.

**M4**. To develop Nutrition and Dietetics leaders with capability of creating value in Nutrition and Dietetics industry.

**Program Educational Objectives:**

**PEO** 1. Graduates shall work as nutritionists and dieticians in various hospitals and health sectors to improve people's health

**PEO** 2. Graduates shall conduct research/ higher studies in Nutrition and Dietetics as well as in the interdisciplinary field to exhibit global competitiveness.

**PEO** 3. Graduates shall possess strong skills in Nutrition and Dietetics and are able to establish their own start-ups.

**Program Specific Objectives:**

**PSO1.** Evaluate critical domestic and global nutritional related issues that challenge and influence the Nutraceutical product development

**PSO2.** Demonstrate competencies in performing the research; evaluating, analysing and presenting the results.

**PSO3.** Effectively communicate and collaborate with health care providers and regulatory agencies to improve people's health and help them make better dietary choices

**PSO4.** Demonstrate regulations, social and ethical values required to make a global nutritional expert

**Program Outcomes:**

**PO**1- Nutrition and Dietetics Knowledge: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of nutrition and dietetics.

**PO**2- Planning Abilities: Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

**PO**3- Problem analysis: Utilize the principles of Analytical thinking, clearly and critically, while solving problems and making decisions during handling patients, Sports person and making food chart for all age groups and also analyze, evaluate and apply information systematically and making decisions related to it.

**PO**4- Modern tool usage: Learn and apply modern and appropriate practical applicable toolsof a scientific understanding of nutrition.

**PO**5- Leadership skills: Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles during the conduction of their job to facilitate improvement in health and wellbeing.

**PO**6- Professional Identity: Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, Clinical Researcher, managers, employers, employees)

**PO**7- Nutrition and Dietetics Ethics: Honor human values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions.

**PO**8- Communication: Communicate effectively with the Nutritional community (healthcare provider, doctor and patient and write effective reports, make effective presentations and documentation, and give and receive clear instructions.

**PO**9- The Nutrition and Dietetics and society: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the Nutritional practice.

**PO**10- Environment and sustainability: Understand the impact of the Nutritional solution in societal and environmental contexts, demonstrate the knowledge of, and need for sustainable development.

**PO**11- Life-long learning: Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self access and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

## Curriculum

| Semester 1 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sl. No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BNDT 1001 | Basics of Nutrition | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BNDT 1002 | Introduction to Healthcare | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BNDT 1003 | Human Physiology-I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BNDP 1051 | Nutrition and Dietetics Lab-I | 0 | 0 | 4 | 2 | 50 | - | 50 |
| 5 | | Disruptive technologies | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 6 | | Professional communication | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 7 | | Environmental Studies | 0 | 0 | 1 | 0.5 | 50 | - | 50 |
| 8 | | Campus to corporate | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 9 | | Ethics and Professional Competency | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 10 | | Creative / Liberal Arts | 0 | 0 | 1 | 0.5 | 50 | - | 50 |
| 11 | | Waste management | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 12 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **20** | **0** | **6** | **23** | | | |
| **Semester II** | | | | | | | | | |
| **Sl No** | **Course Codee** | **Name of the Course** | | | | | **Assessment Pattern** | | |
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| 1 | BNDT2001 | Basic Biochemistry | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BNDT 2002 | Basic Dietetics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BNDT 2003 | Research Methodology and Biostatistics | 4 | 0 | 0 | 4 | 20 | 30 | 50 |
| 4 | BNDT2004 | Food Science-I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | BNDT 2005 | Human Physiology-II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | | Professional communication | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 7 | | Foreign Language | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 8 | BNDP 2051 | Nutrition and Dietetics Lab-II | 0 | 0 | 4 | 2 | 50 | -- | 50 |
| 9 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **22** | **0** | **4** | **24** | | | |
| **Semester III** | | | | | | | | | |
| **Sl No** | **Course Code** | **Name of the Course** | | | | | **Assessment Pattern** | | |
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| 1 | BNDT3001 | Nutraceuticals | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BNDT3002 | Family meal Management | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BNDT3003 | Food Science-II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BNDT3004 | Food Service Management | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | BNDP3051 | Computer Lab | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| 6 | BNDP 3052 | Nutrition and Dietetics Lab-III | 0 | 0 | 4 | 2 | 50 | -- | 50 |
| 7 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 8 | | Disaster Management | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 9 | | AI and its application | 0 | 0 | 4 | 2 | 50 | -- | 50 |
| 10 | | Creativity, Innovation and entrepreneurship and IPR | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **16** | **0** | **10** | **21** | | | |

## School of Computing Science and Engineering

| Semester IV | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sl No** | **Course Code** | **Name of the Course** | | | | | **Assessment Pattern** | | |
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| 1 | BNDT4001 | Food Microbiology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BNDT4002 | Advanced Dietetics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BNDT4003 | Community Nutrition | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BNDT4004 | Pharmacology-I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | BNDP 4051 | Nutrition and Dietetics Lab-IV | 0 | 0 | 4 | 2 | 50 | -- | 50 |
| 6 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | SMCT1001 | Swayam MOOCs Course | 2 | 0 | 0 | 2 | 25 | 00 | 75 |
| | | **Total** | **15** | **0** | **4** | **17** | | | |
| **Semester V** | | | | | | | | | |
| **Sl No** | **Course Code** | **Name of the Course** | | | | | **Assessment Pattern** | | |
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| 1 | BNDT 5001 | Food Standard And Quality Control | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BNDT 5002 | Nutritional Assessment And Surveillance | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BNDT 5003 | Nutritional care in disease condition | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BNDT 5004 | Fundamentals of Clinical Research | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | BNDT 5005 | Hospital and Healthcare Administration | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | BNDT 5006 | Pharmacology –II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 7 | BNDP 5051 | Nutrition and Dietetics Lab-V | 0 | 0 | 4 | 2 | 50 | -- | 50 |
| | | **Total** | **18** | **0** | **4** | **20** | | | |
| **Semester VI** | | | | | | | | | |
| **Sl No** | **Course Code** | **Name of the Course** | | | | | **Assessment Pattern** | | |
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| **1** | BNDP6051 | Project and Dissertation | 0 | 0 | 30 | 15 | 60 | -- | 240 |
| | | **Total** | **0** | **0** | **30** | **15** | | | |

| Name of The Course | Basics of Nutrition | | | |
|---|---|---|---|---|
| Course Code | BNDT1001 | | | |
| Prerequisite | | | | |
| Co-requisite | | | | |
| Anti-requisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**

Students will be exposed to basics of Nutrition and their requirements.

**Course Outcomes**

| | |
|---|---|
| **CO1** | Concepts and definitions of Nutrition |
| **CO2** | Energy balance |
| **CO3** | function of carbohydrate |
| **CO4** | Definition, classification and function of Protein |
| **CO5** | Definition, classification and function of Lipids |
| **CO6** | Definition, classification and function of Vitamins and Minerals |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Exam (MTE) | End Term Exam (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| |
|---|
| **Unit I: Introduction to Nutrition** **7 Hours** |
| Concept and definition of terms Nutrition, Malnutrition and Health. Brief History of Nutritional Science, Scope of Nutrition. Minimal Nutritional Requirements and RDA- Formulation of RDA and Dietary Guidelines- Reference Man and Reference women. |
| **Unit-2 Energy Balance** **7 Hours** |
| Overview, Concept and Definition, Energy Balance, Assessment of Energy Requirements, Deficiency and Excess, Energy Chart flow, Energy Calculation |
| **Unit-3 Carbohydrates** **7 Hours** |
| Carbohydrates- Definition, Classification and functions. Digestion and Absorption, Blood glucose and effect of different carbohydrates on blood glucose. Dietary Fibre - Nutritional significance |
| **Unit-4: Protiens** **7 Hours** |
| Definition, classification and functions. Assessment of protein quality (BV, PER, NPU), Digestion and Absorption, factors affecting protein bio-availability including anti-nutritional factors. Requirements, deficiency. |
| **Unit-5: Lipids** **7 Hours** |

| |
|---|
| Definition, classification and functions of lipids. Digestion and absorption, Intestinal re-synthesis of triglycerides. Types of fatty acids, role and nutritional significance (SFA,MUFA,PUFA, omega-3). |
| **Unit-6: Minerals, Trace Elements And Vitamins** **5 Hours** |
| Minerals - Physiological role, bio-availability and requirements, sources, Deficiency and Excess(Calcium, Phosphorus, Magnesium, Iron, Fluoride, Zinc, Iodine)<br>Vitamins-Physiological role, Bio-availability and requirements, sources, deficiency and excess(Fat soluble and water soluble) |

**Suggested Reading**

1. Shubhangini A. Joshi,(1992)' "Nutrition and Dietetics"Tata Mc Grow- Hill publishing Company Ltd, New Delhi.
2. Srilakshmi. B – "Nutrition Science", V Edn, New Age International (P) Ltd, Publishers, Chennai
3. Passmone R.and Eastwood M.A,(1986), "Human Nutrition and Dietetics",English language book Society/Churchill Livingstone,Eigth edition, Hong Kong.
4. Neiman N. Catherine, (1990), "Nutrition",Wm.C. Brown Publishers. USA.

| **Name of The Course** | **Introduction to Healthcare** | | | |
|---|---|---|---|---|
| **Course Code** | **BNDT1002** | | | |
| **Prerequisite** | | | | |
| **Co-requisite** | | | | |
| **Anti-requisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives**

Introduction to Healthcare exposes a student to learn Healthcare system, Hospital Role, Infection control, and foundation of health.

**Course Outcomes**

| | |
|---|---|
| **CO1** | Healthcare systems and Ethical Roles and Responsibilities of a Health Care Worker |
| **CO2** | Holistic Health and Controlling Infection, Mental Health, Nutrition, Controlling Infection |
| **CO3** | Foundation of health and healthcare system, Community Medicine and Hospitals |
| **CO4** | Introduction to Primary healthcare, state & district level including Municipal Corporations & Councils |
| **CO5** | Role of Hospital in healthcare system, National Rural and Urban Health Mission |
| **CO6** | Inventory Control & Purchase Management |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term Exam (MTE)** | **End Term Exam (ETE)** | **Total Marks** |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit I: Healthcare Systems** **7 hours** |
|---|

| |
|---|
| Careers in Health Care, Personal Qualities of a Health Care Worker/Health Care Providers, Measurement, Medical Terminology, Legal Obligations, Cultural Considerations, Medical Liability and Patient's Rights, Ethical Roles and Responsibilities of a Health Care Worker |
| **Unit II:Health Control 7 Hours** |
| Holistic Health, Mental Health, Nutrition, Controlling Infection, Measuring Vital Signs and other Clinical Skills, Injury and Prevention, First Aid/ CPR |
| **Unit III: Foundations of Health and Healthcare System 7 hours** |
| Concept of health & disease: Concept of Prevention, Preventive Medicine, History of Hospitals. Characteristics Hospitals as industry, Community Medicine & Hospitals |
| **Unit IV: Introduction to Primary Health Care 7 hours** |
| Definition, Principles, Functions, Evolution of Health Care System. Organisation of Health Services at central, state & district level including Municipal Corporations & Councils, Panchayat Raj institutions. Inter-sectoral linkages |
| **Unit V:Role of hospitals in health care system 7 hours** |
| National health policy, National Rural and Urban Health Mission. National Health Programmes. International Health Agencies, Concepts of family welfare, National Family Welfare programme. MCH and RCH programmes |
| **Unit VI: Inventory Control & Purchase Management 5 Hours** |
| Inventory Control & Purchase Management-meaning & significance. Purchasing & procurementPrinciples of sourcing, purchase methods & procedures, legal aspects of purchasing. Reference to Contract Act, Sale of Goods Act, Drug Control Act in respect to purchase activities. Import substitution |

**Suggested Reading**


9. 1. Health Care Reforms in India – Rajendra Pratap Gupta
10. Introduction to Health Care – SHARON B. BUCHBINDER & NANCY H. SHANKS
11. Innovation in Health Care Management- VK Singh n Paul Lillrank
12. India's Healthcare Industry – Lawton Robert Burns


| **Name of The Course** | **Human Physiology-I** | | | | |
|---|---|---|---|---|---|
| **Course Code** | **BNDT1003** | | | | |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50 % marks in aggregate | | | | |
| Corequisite | Basic knowledge of physiology. | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

**Course Objectives:** Students are able to understand the basic concept of Physiology and they can apply the knowledge of physiology in understanding the various .diseases and keeping the body in healthy state.

**Course Outcomes**

| | |
|---|---|
| CO1 | Understand the Digestive system. |
| CO2 | Interpret the composition of blood and its function circulatory system of human |

| | |
|---|---|
| CO3 | Interpret the circulatory system in human |
| CO4 | Evaluate the respiratory system |
| CO5 | Understand the excretory system. |
| CO6 | Analyze the Male Reproductive system |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| | |
|---|---|
| Unit-1 Digestive system | **7 Hours** |
| Digestive system – Homeostasis, structure of stomach and intestine, Digestive gland and Hormones, Digestion of food in different parts of alimentary canal, absorption and assimilation. | |
| Unit-2 Blood and circulation | **7 Hours** |
| Blood and circulation - Blood corpuscles, hemopoieses and formed elements, plasma function, blood volume, WBC and platelets function. Anemia, thalassemia, Leukemia, Polycythemia, Hemostasis and blood coagulation mechanism, blood groups and blood banking. hematocrits value | |
| Unit-3 Cardiovascular System | **7 Hours** |
| Cardiovascular System: Comparative anatomy of heart structure, myogenic heart, specialized tissue, ECG – its principle and significance, cardiac cycle, heart as a pump, blood pressure, neural and chemical regulation. | |
| Unit-4 Respiratory system | **7 Hours** |
| Respiratory system – structure of lungs and surfactant function, Mechanism of breathing, anatomical considerations, alveolar ventilation, vital capacity of lungs, transport of gases, exchange of gases, waste elimination, neural and chemical regulation of respiration. | |
| Unit-5 Excretory system | **7 Hours** |
| Excretory system - Comparative physiology of excretion, kidney, urine formation, urine concentration, waste elimination, micturition, regulation of water balance, blood volume, blood pressure, electrolyte balance, acid-base balance. | |
| Unit-6: Male Reproductive system | **5 Hours** |
| Testis, Duct system, Functions. Semen-secretion, composition, Oligozoospermia. | |

**Suggested Readings**


7. Guyton A.C, Hall J.E, Textbook of Medical Physiology, 11th Ed., Saunders Company, 2005.
8. Widmaier E. P, Raff H, Strang K. T. Vander's, Human Physiology : The mechanism of Body Function, 9th Ed. Mc. Graw Hill, 2003.
9. Ganong W. E, Review of Medical Physiology, 21st Ed., Mc. Graw Hill, 2003.


# Semester-II

| | | | | | |
|---|---|---|---|---|---|
| **Name of The Course** | **Basic Biochemistry** | | | | |
| **Course Code** | **BNDT2001** | | | | |
| **Prerequisite** | | | | | |
| **Corequisite** | | | | | |
| **Antirequisite** | | | | | |
| | | **L** | **T** | **P** | **C** |
| | | **3** | **0** | **0** | **3** |

**Course Objectives:**

This course Biochemistry-1 deals with the acid base balance, biochemical nature of carbohydrates, proteins, minerals, vitamins, lipids etc. A detailed study of these, emphasizing on their chemical composition and their role in metabolism is the required aim of this course.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Acid Base balance, Structure, function and interrelationship of bio molecule |
| CO2 | Different types of carbohydrates and their structure and function |
| CO3 | Amino acids & Proteins and Chemical bonds involved in protein Structure |
| CO4 | Types of Lipids, properties & functions of fatty acids, Saturated and Unsaturated Fatty acids and biological significance of fats |
| CO5 | Base Composition of Nucleic acids, deficiency disorders of Vitamins and Minerals |
| CO6 | Analyze the mechanism of enzyme's action |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content:**

| | |
|---|---|
| **Unit-1: Introduction of Acid, Base and Salt** | **7 hours** |
| Introduction, Definition, Structure of Water molecule, basic concept of Acids, bases, salts & acid base balance, buffer System, Structure of cell & introduction to Atoms and chemical bonds. | |
| **Unit-2: Carbohydrates** | **7 hours** |
| Introduction, Sources, Classification, fischer projections, The artificial or synthetic sweeteners, Haworth perspective formula, Isomerism, important derivatives of monosaccharides, Structure and functions of sugars-disaccharides & polysaccharides. | |
| **Unit-3: Amino Acids and Proteins** | **7 hours** |
| Introduction, Classification, Properties of Proteins, Peptide bond, Amino acids, Peptides, Chemical bonds involved in protein Structure, Derived protein, Ramachandran plot, Myoglobin. | |
| **Unit-4 : Lipids** | **7 hours** |
| Introduction, sources, nomenclature, classification, structure, properties & functions of fatty acids, Saturated and Unsaturated Fatty Acids, Derived Lipids, steroids, biological significance of fats ,cholesterol and phospholipids | |
| **Unit-5: Nucleic Acid, Vitamins and Minerals** | **7 hours** |
| Introduction, Definition and Base Composition of Nucleic acids, helical Structure, Nomenclature and Classification of Enzymes, deficiency disorders of Vitamins and Minerals. | |
| **Unit-6: Enzymes** | **5 hours** |
| Structure of enzyme: Apoenzyme and cofactors, prosthetic group-TPP, coenzyme NAD,metal cofactors; Classification of enzymes; Mechanism of action of enzymes: active site, transition state complex and activation energy | |

**Suggested Readings:**

1. S. Ramakrishnan, K G Prasannan and R Rajan: Text book of Medical Biochemistry, Orient Longman, Madras, 1990

2 Das, Debajyothi, Biochemistry, Academic, Publishers, Calcutta.

3 A Text book of Medical Biochemistry by. Chatterjee,

4 A Text book of Biochemistry by Satyanarayan,U.

5 Fundamentals of Biochemistry- J L Jain, Sanjay Jain, Nitin Jain

| | | | | |
|---|---|---|---|---|
| **Name of The Course** | **Basic Dietetics** | | | |
| **Course Code** | **BNDT2002** | | | |
| **Prerequisite** | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:
This subject deals with the basics concepts of diet therapy.

**Course Outcomes:**
After completion of this course work students able to

| | |
|---|---|
| CO1 | Introduction to basic concept of diet therapy |
| CO2 | Routine hospital diet and feeding |
| CO3 | Energy modification and nutritional care |
| CO4 | Different diseases of GI tract |
| CO5 | Modification of diet in infections and surgery |
| CO6 | Understand Etiology and dietary management |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| | |
|---|---|
| **Unit-1: Basic Concepts of Diet Therapy** | 7 hours |
| Therapeutic adaptation of normal diets. Principles and classification of therapeutic diets. | |
| **Unit-2: Routine Hospital Diets and Feeding** | 7 hours |
| Regular diet, light diet, soft diet, fluid diet. Enteral feeding - tube feeding. Parenteral Feeding - Central and peripheral. | |
| **Unit-3: Energy Modifications and Nutritional Care for Weight Management** | 7 hours |
| Identification of overweight and obese- Aetiological factors contributing to obesity and prevention Treatment – Low Energy diets, behavioral modification. Complications of obesity. Underweight – aetiology and assessment. Treatment - high energy diets. Complications - Anorexia Nervosa, Bulimia | |
| **Unit-4: Diseases of the Gastro Intestinal Tract** | 7 hours |
| Etiologic factors, symptoms, diagnostic tests and dietary treatment for Esophagitis and hiatus hernia, Diarrhoea and Constipation – high and low fiber diet. Gastritis, Peptic Ulcer and Ulcerative colitis. Malabsorption Syndrome –Celiac Sprue – Gluten restricted diet, Steatorrhoea- MCT restricted diet | |
| **Unit-5: Modifications of Diet in Infections and Surgery** | 7 hours |
| Fever and infections – aetiology, symptoms, diagnostic tests and dietary treatment – High Protein diet Surgical conditions – Pre-Operative and Post Operative conditions. Burns and Trauma – complications and dietary treatment. Diet in Allergy - Definition, Symptoms, diagnostic tests and dietary management in allergy. Elimination diet and desensitization. | |
| **Unit-6: Etiology, Manifestation and Dietary Management** | 5 hours |

| |
|---|
| Nutritional management of metabolic disease 1: Diabetes and hypoglycemia, Diet Plan Food exchange list, Glycemic index, CHO counting. Meal planning with and without insulin, Artificial sweeteners and sugar substitutes, Drugs and insulin, Exercise<br>Hypoglycemia- Classification, symptoms, Fasting hypoglycemia, Postprandial or reactive hypoglycemia, early alimentary and late reactive hypoglycemia, Idiopathic hypoglycemia. Dietary treatment in reactive hypoglycemia |

**Suggested Readings**:


1. West, E.S. Todd, W.R., Mason, H.S and Van Bruggen, J.T.(1974):4th Ed. Text book of biochemistry, Amerind. Publishing Co Pvt LTd.,]
2. Ambika Shanmugam (1986): Seventh Edition"Fundamentals of Biochemistry" for Medical Student. New Delhi
3. Devlin, T.M. (1986): 2nd Ed.Text Book of Biochemistry with Clinical corrections, John Wiley and sons.
4. Deb.A.C. (1992): fifth Edition, Fundamentals of Bio chemistry, New Central Book Agency(P) ltd.
5. S. Ramakrishnan, K.G Prassanan, R.Rajan,"Text book of Medical Bio chemistry", 1989, second edition, orient Longman limited.


| **Name of The Course** | **Research Methodology & Biostatistics** | | | |
|---|---|---|---|---|
| **Course Code** | **BNDT2003** | | | |
| **Prerequisite** | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 4 | 0 | 0 | 4 |

**Course Objectives**:

Students will get exposure about Research Methodology

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Research |
| CO2 | Understand about the Research Design |
| CO3 | Understand about the Research Report and ethics |
| CO4 | Understand about the Sampling methods |
| CO5 | Understand about the Measures of central tendency |
| CO6 | Understand about Hypothesis testing |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Introduction to Research** | 7 hours |
|---|---|
| Research definition, types, advantage and significance. Introduction to research methods, identifying research problem, definition, objectives, role, scope in biotech research, process of research, limitations & types | |
| **Unit-2: Research Design** | 7 hours |
| Concept of Interdisciplinary Research, Procedures in research. Types of Research Design: Experimental/Interventional research, Quasi-experimental studies, Observational research. Sources of Experimental Errors. Survey research: Types of surveys- CATI, CAPI, Mail, Email, Face-to-face, Questionnaire | |
| **Unit-3: Research Report and ethics** | 5 hours |

| | |
|---|---|
| Type of research report- Research, review, case report, manuscript, monograph, book chapters. Structure of Research Reports. Quoting of reference and bibliography using reference management tools. Ethical issues in research, plagiarism. | |
| **Unit-4: Sampling methods** | 6 hours |
| Sampling methods, Advantages and Limitation, Sampling process, Types of Sampling, Probability and Non Probability sampling techniques, sampling errors, Data collection Primary and secondary data, Collection and validation. | |
| **Unit-5: Measures of central tendency** | 8 hours |
| Measures of central tendency- Mean, Median, Mode; Measures of dispersion- Range, Mean deviation and Coefficient of variation, Standard deviation, Standard error; Correlation and regression; Statistical inference- Hypothesis testing, Significance level, Confidence interval, t-test, z-test. Test of significance for large and small samples; Parametric tests; Non parametric tests; Experimental design, Use of biostatistic softwares. | |
| **Unit-6: Hypothesis testing** | 7 hours |
| Null hypothesis and test of significance (t-test, paired t-test, Analysis of variance, Analysis of covariance, Coefficient of Variation, chi-square test, Fischer exact, Mann-Whitney, Wilcoxin, McNeman test, Kruskal Wallis. | |

**Suggested Readings**:


13. Graziano AM, Raulin ML. Research methods: A process of inquiry. HarperCollins College Publishers; 1993.
14. C.R. Kothari : Research Methodology, New Age International Publishers
15. Bouma GD, Ling R, Wilkinson L. The research process. Oxford: Oxford University Press; 1993 Mar 30.
16. Dawson B, Trapp RG. Basic and clinical biostatistics. Singapore. 2004;2001:141-2.


| | | | | | |
|---|---|---|---|---|---|
| **Name of The Course** | **Food Science-I** | | | | |
| **Course Code** | **BNDT2004** | | | | |
| **Prerequisite** | | | | | |
| **Corequisite** | | | | | |
| **Antirequisite** | | | | | |
| | **L** | **T** | **P** | **C** | |
| | **3** | **0** | **0** | **3** | |

**Course Objectives:**

This subject will develop an understanding of concepts and importance of different food.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Definition, functions, food groups, classification of foods |
| CO2 | Importance of Pulses |
| CO3 | Importance of Milk and Milk Products |
| CO4 | Importance of egg, fish, poultry and meat |
| CO5 | Importance of Vegetables and fruits |
| CO6 | Inborn errors of metabolism, Older children and adolescents |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| | |
|---|---|
| **Unit-1: INTRODUCTION TO FOODS** | **7 hours** |

| |
|---|
| Definition, functions, food groups, classification of foods. Study of different cooking methods, merits and demerits, Solar cooking, Microwave cooking. Cereals - Cereals and millets- breakfast cereals, cereal products, fast foods- structure, processing, use in variety of preparation, selection, variety, storage, nutritional aspects and cost |
| **Unit-2: PULSES 7 hours** |
| Pulses and legumes- Production (in brief), Selection and variety, storage, processing, use in variety of preparation, nutritional aspects and cost. Highlighting soya beans, lathyrism- removal of toxins. |
| **Unit-3: MILK AND MILK PRODUCTS 7 hours** |
| Composition, classification, quality, processing, coagulation of milk, digestion of milk, storage, uses and cost. Nutritional aspects of milk, curd, butter, paneer, khoa, cheese, ice cream, kulfi and various kinds of processed milk. |
| **Unit-4 : EGG, FISH, POULTRY AND MEAT 7 hours** |
| Selection, quality, purchase, storage, uses and nutritional aspects. Spoilage of egg, fish, poultry and meat. |
| **Unit-5: Vegetables and Fruits 6 hours** |
| Variety, selection, purchase, storage, availability, cost, use and nutritional aspects of raw and processed vegetables and fruits. Effects of cooking on colour, texture, flavour, appearance and nutritive value. |
| **Unit-6: Inborn errors of metabolism, Older children and adolescents 6 hours** |
| Introduction, clinical features, dietary management of phenylketonuria, Galactosemia, Alkaptonuria<br>Infants and preschool children, Feeding 0-6 months infant, Feeding 6-12 months infant, Feeding preschoolers, Problems of infants and preschoolers nutrition |

**Suggested Readings**

1. Swaminathan (1995): “Food & Nutrition”, The Bangalore Printing & publishing co ltd., Vol I, Second Edition, Bangalore.

2. Srilakshmi (1997): “Food Science”, New Age International (P) Ltd, Publishers, Pune.

3. Mudambi .R. Sumathi & Rajagpal M.V (1983), “Foods & Nutrition”, Willey Eastern Ltd, Second Edition, New Delhi.

4. Thangam.E.Philip(1965): Modern Cookery, Orient Longman, II edition. Vol II

| | | | | |
|---|---|---|---|---|
| **Name of The** | **HUMAN PHYSIOLOGY-II** | | | |
| **Course Code** | **BNDT2005** | | | |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50 % marks in aggregate. | | | |
| Corequisite | Basic knowledge of human physiology | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**: Students are able to understand the basic concept of Physiology and they can apply the knowledge of physiology in understanding the various diseases and keeping the body in healthy state.

**Course Outcomes**

Students are able to

| | |
|---|---|
| CO1 | Describe Structure of Neurons, action potential, Neurotransmitter |
| CO2 | Explain Mechanism of Muscle contraction in skeletal tissue |
| CO3 | Describe Structure and functional anatomy of eye and ear |
| CO4 | Explains Endocrinology including hormones and their action |
| CO5 | Explain Reproductive processes |
| CO6 | Understand the Skeletal physiology |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1 Nervous system** | **7 hours** |
|---|---|
| Nervous system: Structure of Neurons, action potential, Neurotransmitter, gross neuroanatomy of the brain and spinal cord, central and peripheral nervous system, Structure of cerebrum and function of different area of cerebral cortex, memory and cognition, Thermoregulation, mechanism of thermo sensation pathways. | |
| **Unit-2 Muscle physiology** | **7 hours** |
| Muscle physiology: Mechanism of Muscle contraction in skeletal tissue, structural and function difference between skeletal muscle and cardiac muscle. Structure of actin and myosin filament, Tetany, muscular dystrophy. | |
| **Unit-3 Sensory system** | **7 hours** |
| Sensory system: Functional anatomy of eye, Structure and functional anatomy of retina, Structure of rod and cone cells and their pigments, Molecular mechanism of rhodopsin, mechanism of Vision, hyperpolarization of rod receptor potential, Functional anatomy of ear; structure and function of organ of corti, Inner hair cells (IHC) and outer hair cells (OHC) stereocilia, mechanism of Hearing. Common disorders of the following sensations: Vision, Hearing, Taste, Smell and Touch | |
| **Unit-4 Endocrine System** | **7 hours** |
| Endocrinology: Endocrine glands: Pituitary gland and hormone, thyroid gland and its hormone, adrenal gland and its hormone function, basic mechanism of hormone action, hormones and diseases. | |
| **Unit-5 Female Reproductive system** | **7 hours** |
| Reproductive system: Reproductive processes, gametogenesis, ovulation, neuroendocrine regulation, Menstrual cycle, Hormones related to ovulation and reproductive cycle. | |
| **Unit-6 Skeletal physiology** | **5 hours** |
| Cartilage – types with example & histology, Bone – Classification, names of bone cells, parts of long bone, microscopy of compact bone, names of bones, vertebral column, fontanelles of fetal skull, Joints – Classification with examples | |

**Suggested Readings:**


7. Guyton A.C, Hall J.E, Textbook of Medical Physiology, 11th Ed., Saunders Company, 2005.
8. Widmaier E. P, Raff H, Strang K. T. Vander's, Human Physiology : The mechanism of Body Function, 9th Ed. Mc. Graw Hill, 2003.
9. Ganong W. E, Review of Medical Physiology, 21st Ed., Mc. Graw Hill, 2003.


# Semester III

| Name of The Course | **Nutraceuticals** | | | |
|---|---|---|---|---|
| Course Code | **MNAD3001** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**

Students will get exposure about the neutraceutical and functional food in different disease condition.

**Course Outcomes**

| CO1 | Basics of Nutraceuticals as Science |
|---|---|

| | |
|---|---|
| CO2 | Properties, structure and functions of various Nutraceuticals |
| CO3 | Food as remedies |
| CO4 | Anti-nutritional Factors present in Foods |
| CO5 | Development of Novel Food and food Ingredients: Polysaccharides, low caloric sweeteners |
| CO6 | Nutraceutical industries in India and abroad |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| **Unit 1 Introduction to Nutraceuticals as Science 7 Hrs** |
| Historical perspective, classification, scope & future prospects. Applied aspects of the Nutraceutical Science. Sources of Nutraceuticals. Relation of Nutraceutical Science with other Sciences: Medicine, Human physiology, genetics, food technology, chemistry and nutrition. |
| **Unit 2: Properties, structure and functions of various Nutraceuticals 7 Hrs** |
| Glucosamine, Octacosanol, Lycopene, Carnitine, Melatonin and Ornithine alpha ketoglutarate. Use of proanthocyanidins, grape products, flaxseed oil as Nutraceuticals. |
| **Unit 3: Food as remedies 7 Hrs** |
| Nutraceuticals bridging the gap between food and drug, Nutraceuticals in treatment for cognitive decline, Nutraceutical remedies for common disorders like Arthritis, Bronchitis, circulatory problems, hypoglycemia, Nephrological disorders, Liver disorders, Osteoporosis, Psoriasis and Ulcers etc. Brief idea about some Nutraceutical rich supplements e.g. Bee pollen, Caffeine, Green tea, Lecithin, Mushroom extract, Chlorophyll, Kelp and Spirulina etc. |
| **Unit 4: Anti-nutritional Factors present in Foods 7 Hrs** |
| Types of inhibitors present in various foods and how they can be inactivated. General idea about role of Probiotics and Prebiotics as nutraceuticals. Recent advances in techniques & feeding of substrates. Assessment of nutritional status and Recommended Daily allowances. |
| **Unit 5: Development of Novel Food and food Ingredients: Polysaccharides, low caloric sweeteners 7 Hrs** |
| Naturally produced flavor modifiers, Single Cell Proteins, Marine algae as food supplements, Food supplements and food Ingredients as byproducts – Fishery, poultry/animal husbandry and agriculture/dairy industries. |
| **Unit 6: Nutraceutical industries in India and abroad 5 Hrs** |
| Reputed Indian and International industries involved in production and development of Nutraceuticals and functional foods |

**Suggested Readings:**

1) Nutraceuticals: Efficacy, Safety and Toxicity by Ramesh C. Gupta
2) Nutraceuticals: The Complete Encyclopedia of Supplements, Herbs, Vitamins and Healing Foods by Arthur J. Roberts, Genelle Subak-Sharpe, et al.
3) Advances in Nutraceutical Applications in Cancer: Recent Research Trends and Clinical Applications (Nutraceuticals) by Sheeba Varghese Gupta and Yashwant V Pathak
4) Nutraceuticals in Health and Disease Prevention (Infectious Disease and Therapy Book 6) by PETER. PAUL HOPPE, Klaus Kramer, et al.
5) Nutrigenomics and Nutraceuticals: Clinical Relevance and Disease Prevention by Yashwant V. Pathak and Ali M. Ardekani

6) Pharmaceuticals to Nutraceuticals: A Shift in Disease Prevention by Dilip Ghosh and R. B. Smarta
7) Handbook of Nutraceuticals and Functional Foods (Modern Nutrition) by Robert E.C. Wildman and Richard S. Bruno

| **Name of The Course** | **Family meal Management** | | | | |
|---|---|---|---|---|---|
| **Course Code** | **BNDT3002** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

**Course Objectives:**
This course deals with the basic concept of family meal and menu planning

**Course Outcomes:**
After completion of this course work students able to understand

| | |
|---|---|
| CO1 | Factors to be considered in meal |
| CO2 | nutrition requirements in pregnancy and nutrition |
| CO3 | Nutrition in infancy and childhood |
| CO4 | Nutrition for school children |
| CO5 | Nutrition for geriatric population |
| CO6 | Nutritional Genomics |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit-1: Basic Principles of Meal and Menu Planning** | **5 hours** |
|---|---|
| Factors to be considered in meal/menu planning. | |
| **Unit-2: Nutrition in Pregnancy and Lactation** | **7 hours** |
| Pregnancy - Physiological stages of pregnancy, nutrition requirements food selection and Complications of pregnancy. Lactation - Physiology of lactation, nutritional requirements | |
| **Unit-3: Nutrition During Infancy and Early Childhood** | **7 hours** |
| Infancy - Growth and development, nutritional requirements, breast feeding, infant formula. Introduction of supplementary foods.<br>Early childhood. (Toddlers and Preschoolers) - Growth and nutrient needs, nutritional related problems, Feeding Pattern | |
| **Unit-4: Nutrition for School Children and Adolescence** | **7 hours** |
| Mortality, sociodemographic information, Disease trends and standardization, Mortality ratio, Random error/chance: samples size and statistical power, type I and II errors, regression dilution, confidence intervals | |
| **Unit-5: Geriatic Nutrition** | **7 hours** |
| Factors affecting food intake and nutrients use, nutrient needs, nutrition related problems. | |
| **Unit-6: Nutritional Genomics** | **7 hours** |
| Production technology for recombinant therapeutic products using E.coli with examples like human insulin, growth hormones, interferons, erythropoietin | |

**Suggested Readings**


1. Shubangini A Joshi, (1998): Nutrition and Dietetics, Tata Mc Graw Hill Pub. Co. Ltd., New Delhi.
2. National Institute of Nutrition, (2005): Dietary Guidelines for Indians – A Manual, Hyderabad.
3. Srilakshmi. B, (2005): Dietetics, V Edition, New Age International (P) Ltd, Publishers, Chennai.
4. Mahan, L.K. and Escott-Stump, S. (2000) Krause's Food, Nutrition and Diet Therapy, 10th Ed.W.B.Saunders Company, London.
5. Williams S.R. (1993): Nutrition and Diet Therapy, 7th Ed. Times Mirror / Mosby College Publishing, St. Louis.
6. Antia F.P, Clinical Dietetics and Nutrition, Oxford University Press.
7. Shills, M.E, Oslon, J.A, Shike, M and Ross, A.C. (1999): Modern Nutrition in Health and Disease, 9th Edition.


| **Name of The Course** | **Food Science-II** | | | | |
|---|---|---|---|---|---|
| **Course Code** | **BNDT3003** | | | | |
| **Prerequisite** | | | | | |
| **Corequisite** | | | | | |
| **Antirequisite** | | | | | |
| | **L** | **T** | **P** | **C** | |
| | **3** | **0** | **0** | **3** | |

**Course Objectives:**

This course deals with the concept of food science

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Sugar and suger cookery |
| CO2 | Fats and oils |
| CO3 | Raising agents and food adjuncts |
| CO4 | Convenience food |
| CO5 | Tea, coffee, chocolate and cocoa |
| CO6 | Application of bioprocess technology in nutraceuticals |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term Test (MTE)** | **End Term Test (ETE)** | **Total Marks** |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content:**

| **Unit-1: SUGAR AND SUGAR cookery** **7 hours** |
|---|
| Different forms of sugar (sugar, jaggery, honey syrup) manufactures, selection, storage and use as preservatives. Stages of sugar cooking. |
| **Unit-2: FATS AND OILS** **7 hours** |
| Types of fats and oils (animal and vegetable), processing and changes (hydrogenation, rancidity, smoking point, emulsification), uses, storage, cost and nutritional aspects. Nuts and oilseeds: Nutritive value and toxins. |
| **Unit-3: RAISING AGENTS AND FOOD ADJUNCTS** **7 hours** |
| Raising agents - Types, constituents, uses in cookery and bakery, different types of cakes- sponge, chiffon and shortened cakes. Food Adjuncts - Spices, condiments, herbs, extracts, concentrates, essences and food colours- origin, classification, description uses, specification, procurement and storage. |
| **Unit-4 : CONVENIENCE FOODS** **7 hours** |

| |
|---|
| Role, types, advantages, uses, cost and contribution to diet. |
| **Unit-5: TEA, COFFEE, CHOCOLATE & COCOA 7 hours** |
| Cultivation, processing, cost and nutritional aspects. |
| **Unit-6: Application of bioprocess technology in nutraceuticals 5 hours** |
| Application of bioprocess technology for production and enhancement of properties of nutraceuticals |

**Text Book (s)**


1. Swaminathan (1995): "Food & Nutrition", The Bangalore Printing & publishing co. ltd., Vol I, Second Edition, Bangalore.
2. Srilakshmi (1997): "Food Science" , New Age International (P) Ltd,Publishers,Pune.
3. Mudambi .R. Sumathi & Rajagpal M.V (1983), "Foods & Nutrition", Willey Eastern Ltd, Second Edition, New Delhi.
4. Thangam.E.Philip(1965): Modern Cookery, Orient Longman, II edition. Vol II, Bombay.


| | | | | |
|---|---|---|---|---|
| **Name of The Course** | **Food Service Management** | | | |
| **Course Code** | **BNDT3004** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | **3** | **0** | **0** | **3** |

**Course Objectives:**

This course deals with the food service management, history and development of food service industry.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | History and development of food service industry. |
| CO2 | Different food service styles |
| CO3 | Layout of food service unit |
| CO4 | Organization and management of food service unit |
| CO5 | Cost control of food |
| CO6 | Functional Foods |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content:**

| |
|---|
| **Unit-1: FOOD SERVICE INDUSTRY 7 hours** |
| Types of catering, History and development. Commercial: Hotels, motels, restaurants, clubs, cafeteria, franchise and chain hotels.Welfare: Hospitals, school lunch, residential establishments, industrial and philanthropic establishments. Transport: Air, Rail and Sea and Space. Miscellaneous: Contract and outdoor catering |
| **Unit-2: FOOD SERVICE STYLES 7 hours** |
| Conventional, Commissary, assembly- line, table service, hatch and counter, cafeteria, banquet, buffet, Indian, western and oriented services. |
| **Unit-3: PLANT LAYOUT, HYGIENE AND SANITATION 7 hours** |

| |
|---|
| Layout of food service units – planning of areas as work units with relevant spacing. Equipment – major and minor – their selection, layout, use and care. Fuels. Hygiene and Sanitation - In food handling, plant, equipment, personnel, raw materials, and methods of work. |
| **Unit-4 : ORGANISATION AND MANAGEMENT 7 hours** |
| Organisation and management - Types and tools – mainly related to food service units. Work simplification and motion study in work areas. Personnel Management – selection, induction, training supervision and dismissal. Legal controls – Labour laws and welfare measures. |
| **Unit-5: FINANCIAL MANAGEMENT 7 hours** |
| Cost control – food costs, overheads and profits. Budgeting, books of account, inventories. Stores control, indents, Purchase. |
| **Unit-6: Functional Foods 5 hours** |
| Definition, Relation of functional foods & Nutraceutical (FFN) to foods & drugs. Applications of herbs to functional foods. Concept of free radicals and antioxidants; Nutritive and Non-nutritive food components with potential health effects. Effect of processing on Nutrients. Soy proteins and soy isoflavones in human health; Role of nuts in cardiovascular disease prevention. Functional foods from wheat and rice and their health effects. Role of Dietary fibers in disease prevention. |

**Suggested Readings:**

1. Hitchcock, M.J (1980): Food service systems administration, Macmillan, New York
2. Sethi, M. Machan, S.(1993): Catering Management: An Integrated approach, Wiley Eastern: New Delhi.
3. West B.B , wood, L.Revised by Hargar V.F, Shugart, G.S, Payne Palacio, J.(1989): "Food service Institution, 6th edition, Macmillan publishing co., New York.
4. Kotas, R(1972): Accounting in theHotel and Catering Industry, Inter text books, 3rd Edition, Butler & Tanner, London.

# Semester IV

| | | | | | |
|---|---|---|---|---|---|
| **Name of The Course** | **Food Microbiology** | | | | |
| **Course Code** | **BNDT4001** | | | | |
| **Prerequisite** | | | | | |
| **Corequisite** | | | | | |
| **Antirequisite** | | | | | |
| | **L** | **T** | **P** | **C** | |
| | **3** | **0** | **0** | **3** | |

**Course Objectives:**

This course deals with the basic concept of food microbiology

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | History of microbiology |
| CO2 | Morphology of microorganism |
| CO3 | Microbiology of different food |
| CO4 | Concept of sterilization and disinfection |
| CO5 | Importance of food hygiene and sanitization |
| CO6 | New technologies in development of Nutraceuticals and functional foods |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| | |
|---|---|
| **Unit-1: Introduction to Microbiology** | **7 hours** |
| Brief history of microbiology - Louis Pasteur, Robert Koch, Edward Jenner. Pure culture techniques and maintenance of cultures. | |
| **Unit-2: Morphology of Microorganisms** | **7 hours** |
| Classification, growth and multiplication, growth curve. Effects of environmental factors on growth of microorganism - pH, aw , redox potential, temperature, oxygen, time and nutrients present in the substrate. Characteristics - Bacteria, Fungi - mucor, rhizopus, aspergillus, pencillium. Yeasts - sacchromyces. Algae- chalmydomonas, spirogyra. Animal viruses and Bacteriophages - classification and replication. Protozoa - entamoeba histolytica, paramecium, plasmodium. Role of microorganisms in food processing and product development. Beneficial effect of bacteria, fungi algae and yeasts. | |
| **Unit-3: Microbiology of Different Foods** | **7 hours** |
| Sources of contamination and spoilage of: Cereal and cereal products like bread, flour and bakery products; Sugar and sugar products like honey, maple syrup and candies; Vegetables and fruits; Meat products like sausage, bacon and ham, fish, egg and poultry; Milk and its products; Canned foods. Food poisoning and food borne infection | |
| **Unit-4 : Control of Microorganisms** | **7 hours** |
| Concepts of sterilization and disinfection, methods of sterilization and disinfection. Common disinfectants used in home and at industries. Tests to identify the effectiveness of sterilization and disinfection. Normal microbiological criteria for food consumption, testing milk and water for quality. | |
| **Unit-5: Food Hygiene and Sanitation** | **7 hours** |
| Importance of food hygiene and sanitation with relevance to food industry. General principles of food hygiene in rural and urban areas in relation to food preparation, processing, packaging, storage and transport and personal hygiene. Hygiene and sanitation with relevance to the physical structures of the site and building. | |
| **Unit-6: New technologies in development of Nutraceuticals and functional foods** | **5 hours** |
| Supercritical food extraction technology-basics and application for extraction of nutraceuticals from various sources, Application of pressurized low polarity water extraction, use of membranes separation technology, distillation and dehydration technologies | |

**Suggested Readings:**

1. Joshua A K., (2000): Microbiology, Popular Book Depot, Chennai.
2. Ananthanarayanan R and Panicker C K J., Textbook of Microbiology, Orient Longman, Chennai.
3. Frazier W C., (2002): Food Microbiology, Mc Graw Hill Book Co., 6th edition, N.Delhi.
4. Pelezar, M.I and Reid, R.D, (1993): Microbiology, 5th edition, McGRaw Hill Book Company, New York.
5. Jay, James, M (2000): Modern Food Microbiology, 2nd edition, CBS Publisher.

| | | | | | |
|---|---|---|---|---|---|
| **Name of The Course** | **Advanced Dietetics** | | | | |
| **Course Code** | **BNDT4002** | | | | |
| **Prerequisite** | | | | | |
| **Corequisite** | | | | | |
| **Antirequisite** | | | | | |
| | | **L** | **T** | **P** | **C** |
| | | **3** | **0** | **0** | **3** |

**Course Objectives:**

This course deals with the diet planning with different diseases.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Diet in relation to deficiency diseases |
| CO2 | Diet in diseases of cardiovascular system |
| CO3 | Diet in diseases of kidney |
| CO4 | Diet in diseases of pancreas |
| CO5 | Nutrition in cancer and aid |
| CO6 | Diet in diseases of liver |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| |
|---|
| **Unit-1: Diet in Relation to Deficiency Diseases** **7 hours** |
| Pathogenesis and dietary management in Nutritional Anemia, PEM, Vitamin A deficiency. |
| **Unit-2: Diseases of Cardio Vascular System** **7 hours** |
| Aetiological factors, symptoms, diagnostic tests and dietary treatment for Atherosclerosis, Ischemic Heart Disease, Congestive Cardiac Failure, Hypertension, High fibre, low fat, Sodium restricted diet. |
| **Unit-3: Diseases of the Kidney** **7 hours** |
| Aetiological factors, symptoms, diagnostic tests and dietary treatment for Acute and chronic Glomerulonephrities. - Low Sodium and low potassium diet. Nephrotic Syndrome.<br>Acute and chronic Renal Failure- uremia. Nephorolithiasis and urolithiasis.<br>Kidney transplantation and Dialysis.<br>Use of Sodium and Potassium exchange lists. |
| **Unit-4 : Disease of the Pancreas and Liver** **7 hours** |
| Diabetes Mellitus - Classification, Aetiological factors, symptoms, diagnostic tests, metabolic changes in the body, Insulin and oral hypoglycaemic drugs. Dietary Modifications with and without insulin, Complications of Diabetes, Food Exchange List. Glycemic Index and its use. Pancreatitis |
| **Unit-5: Nutrition in Cancer and Aids** **7 hours** |
| Aetiological factors, Symptoms, Diagnostic tests and Dietary Management. |
| **Unit-6: Diseases of the Liver** **5 hours** |
| Liver - Aetiological factors, symptoms, diagnostic tests and dietary treatment for Viral Hepatitis, Cirrhosis of the liver and liver encephalopathy – high carbohydrate diet. Cholelithiasis and cholecystitis – low fat diet |

**Suggested Readings:**


1. Shubangini A Joshi, (1998): Nutrition and Dietetics, Tata Mc Graw Hill Pub. Co. Ltd., New Delhi.
2. National Institute of Nutrition, (2005): Dietary Guidelines for Indians – A Manual, Hyderabad.
3. Srilakshmi. B, (2005): Dietetics, V Edition, New Age International (P) Ltd, Publishers, Chennai.
4. Mahan, L.K. and Escott-Stump, S. (2000) Krause's Food, Nutrition and Diet Therapy, 10th Ed.W.B.Saunders Company, London.
5. Williams S.R. (1993): Nutrition and Diet Therapy, 7th Ed. Times Mirror / Mosby College Publishing, St. Louis.
6. Antia F.P, Clinical Dietetics and Nutrition, Oxford University Press.
7. Shills, M.E, Oslon, J.A, Shike, M and Ross, A.C. (1999): Modern Nutrition in Health and Disease, 9th Edition.

| | | | | | |
|---|---|---|---|---|---|
| **Name of The Course** | **Community Nutrition** | | | | |
| **Course Code** | **BNDT4003** | | | | |
| **Prerequisite** | | | | | |
| **Corequisite** | | | | | |
| **Antirequisite** | | | | | |
| | **L** | **T** | **P** | **C** | |
| | **3** | **0** | **0** | **3** | |

**Course Objectives:**

This course deals with the diet planning with different diseases.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Concept and scope of community nutrition |
| CO2 | Nutritional problem of the community |
| CO3 | Schemes And Programs To Combat Nutritional Problems In India |
| CO4 | Hazards to community health and nutritional status |
| CO5 | Importance of nutrition education in community |
| CO6 | Functional Foods |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| |
|---|
| **Unit-1: Concept and Scope of Community Nutrition** **7 hours** |
| Nutritional Status of a community<br>Methods and techniques used to determine the Nutritional status of a community |
| **Unit-2: Nutritional Problems of the Community** **7 hours** |
| Common problems in India - Causes - Nutritional and non-nutritional. Incidence of nutritional problems, signs and symptoms, treatment – PEM, Micro-nutrient deficiencies(Vitamin A, Iron, Iodine), Fluorosis |
| **Unit-3: Schemes and Programs to Combat Nutritional Problems in India** **7 hours** |
| Prophylaxis programmes, Midday meal programme, ICDS |
| **Unit-4: Hazards to Community Health and Nutritional Status** **7 hours** |
| Adulteration in food, Pollution of water, Industrial effluents, sewage Pesticide residues in food |
| **Unit-5: Nutrition Education** **7 hours** |
| Scope, Objective, Methods available and evaluation. Nutrition policy in India and plan of action |
| **Unit-6: Functional Foods** **5 hours** |
| Sources and role of Isoprenoids, Isoflavones, Flavonoids, carotenoids, Tocotrienols, polyunsaturated fatty acids, sphingolipids, lecithin, choline. terpenoids. Vegetables, Cereals, milk and dairy products as Functional foods. Health effects of common beans, Capsicum annum, mustards, Ginseng, garlic, grape, citrus fruits, fish oils, and sea foods. |

**Suggested Readings:**

1. Jelliffle, D.B(1968): Child Health in the tropics.
2. Ghosh, S(1989): You and your child.
3. Misra, S.K. and puri, V.K(1992): Indian Economy
4. Thankamma Jacob (1976): Food Adulteration.

5. Park, J.E. and Park, K(1994): Text book of Preventive and Social Medicine.
6. Prevention of Food Adulteration Act (1994): Govt of India.

| | | | | |
|---|---|---|---|---|
| **Name of The Course** | **PHARMACOLOGY – I** | | | |
| **Course Code** | **BNDT4004** | | | |
| **Prerequisite** | | | | |
| **Corequisite** | | | | |
| **Antirequisite** | | | | |
| **L** | **T** | **P** | **C** | |
| **3** | **0** | **0** | **3** | |

**Course Objectives:**

This subject deals with the pharmacology of cardiac glycoside drugs e.g. digitoxin, digoxin, antianginal drugs e.g. nitrates, antihyperlipidemic drug e.g. statins, antiarrhythmic drugs e.g. lidocaine, Anticoagulants e.g. heparin, Fibrinolytics e.g. streptokinase, Antiplatelet drugs e.g. Aspirin, Antiasthmatic drugs e.g. bronchodilators, Anti-tussive drugs- opioids(codeine). It also deals with the anti-inflammatory, analgesic, antipyretic drugs and drugs used for migraine treatment e.g. NSAIDS. Drugs acting on GIT antacids- sodium bicarbonate, anti ulcer drug-cimetidine, omeprazole, antiemetics- hyoscine.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | the definition of pharmaco-therapeutics, clinical pharmacology and nomenclature related to pharmacology |
| CO2 | different routes of drug administration, rational/irrational prescribing and fixed dose combination |
| CO3 | Different dosage forms of drugs, their advantage and disadvantages |
| CO4 | principle and mechanism of drug action, factors modifying drug action |
| CO5 | the concept of ADME, bioavailability of drug, receptor and protein blinding |
| CO6 | Analyze the Novel drug delivery system |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| |
|---|
| **Unit-1 Introduction to Pharmacology** **7 hours** |
| Definitions and brief, pharmaco-therapeutics, clinical pharmacology, chemotherapy, pharmacy and toxicology), drug Nomenclature (chemical name, non-proprietary name and proprietary name) and essential drugs concepts. |
| **Unit-2 Drug Administration** **7 hours** |
| Route of Drug administration- Local routes (topical, deeper tissues and arterial supply etc.),<br>Systemic routes (Oral, sublingual, rectal, cutaneous, inhalation, nasal, parenteral etc.),<br>Novel Drug Delivery System, Sources of Drugs (Natural sources and synthetic sources).<br>Rational prescribing, Irrational prescribing, Instruction to patients, Fixed Drug<br>Combination: Advantages & disadvantages; Drugs used in Special Conditions. |
| **Unit-3 Dosage Forms of Drug** **7 hours** |
| Definition and brief about the dosage forms – solid dosage forms (powder, tablets, capsules, lozenges, pills, cachets), liquid dosage forms (suspension, emulsion, elixirs, syrups, lotions, inhalations, eye drops, ear drops, enemas, mouth washes etc.), semisolid dosage forms (ointments, creams, pastes, gels, suppositories, etc.), sterile products (Injection, ophthalmic etc.), gas (aerosols, inhalations, sprays etc.) |
| **Unit-4 Pharmacodynamics** **7 hours** |

| |
|---|
| Principles of drug action and mechanism of drug action, dose response curve and adverse drug reaction, Agonists, Antagonists. Therapeutic Index Factors Modifying Drug Action, Body size, age, sex, species and race, genetics, environmental factors, psychological factor, pathological states, other drugs, cummulation, tolerance, etc |
| **Unit-5: Pharmacokinetics** **7 hours** |
| Absorption, Distribution, Metabolism, excretion (ADME), Bioavailability, receptor and Protein binding, Placental and blood brain barrier |
| **Unit-6: Novel drug delivery system** **5 hours** |
| Novel drug delivery system (liposome, nanosome, nanoparticles, microspheres, osmotic pumps, transdermal, implants, intrauterine devices) |

**Suggested Readings:**

**1** Tripathi K.D., Essentials of Medical Pharmacology, Jay Pee Publishers, New Delhi.

2. Rang M.P., Date M.M., Riter J.M., Pharmacology, Churchill Livingstone.
3. Katzung, B.G., Basic & Clinical Pharmacology, Prentice Hall, International.
4. Barar F.S.K., Text Book of Pharmacology, Interprint, New Delhi.
5. Satoskar & Bhandarkar, Pharmacology & *Pharmacotherapeutics*, Popular Prakashan Pvt. Ltd., Bombay

# Semester V

| | | | | | |
|---|---|---|---|---|---|
| **Name of The Course** | **Food Standard And Quality Control** | | | | |
| **Course Code** | **BNDT5001** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

**Course Objectives**:

This course deals with the Food standards and quality control

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Food quality and quality control |
| CO2 | Index of nutritional quality |
| CO3 | Standards of Food |
| CO4 | Microbiological quality control of food |
| CO5 | Nutritional changes of food during processing |
| CO6 | |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| | |
|---|---|
| **Unit-1: Food Quality and Quality Control** | **7 hours** |

| | |
|---|---|
| Meaning, objectives, important considerations, principles of – quality control of food, raw material and inspection of finished products. Total Quality Management (TQM) - Parameters, evolution, elements TQM, need for TQM and of implementation of TQM in the food industries | |
| **Unit-2: Index of Nutritional Quality (INQ)** | **7 hours** |
| Need for INQ, INQ as an evaluating tool in the food industry, nutrition labeling of foods. Methods of assessing food quality - Cereals and Pulses, fruits and vegetables, milk, meat and its products, egg, Oils, fats, nuts and oilseeds. | |
| **Unit-3: Standard of Foods** | **7 hours** |
| Cereals and Pulses, fruits and fruits products, vegetable and vegetable products, coffee, tea, sugar and sugar products, milk and milk products, eggs and selected fleshy foods. | |
| **Unit-4: Microbiological Quality Control of Foods** | **7 hours** |
| Fundamentals and Principles, factors influencing microbial association with foods, control of micro-flora at different stages of processing. Hazards Analysis and Critical Control Points (HACCP) - Meaning, Quality evaluation, steps involved in HACCP, Implementation and problems in HACCP | |
| **Unit-5: Nutritional Changes in Foods During Processing** | **7 hours** |
| Nutritional losses, nutritional gains, changes in the physical, chemical properties and organoleptic qualities of foods due to processing. | |
| **Unit-6: Patient Satisfaction** | **5 hours** |
| Patient Satisfaction Rights and Responsibilities of Patients Satisfaction and Delight Quality Indicators of Patient Satisfaction | |

**Suggested Readings**


1. Ranganna, S, Manual of analysis of fruits and vegetable products, Mc. Graw Hill International Publishers, New Delhi, 1986.
2. Gaurth Hansen, Bontia. W. Wyse and Ann. W, Sorrenson, Nutritional Quality Control, AVI Publishing and co, Connecticut,1979.
3. Manoranjan Kalia, Food Analysis and Quality, Kalyani Publishers, New Delhi, 2002.
4. Amihud Kramer and Bernard A – Twigg, Quality control for the Food Industry, AVI publishing and Co, Connecticut, 1973.
5. Eugene,L, Grant and Richard L, Leavenworth, Stastical quality control, Mc.Graw Hill International Publishers, 1979.
6. Herschdoerfer, S.M, Quality Control in the Food Industry,vol,1, Academic press,1984.


| | | | | | |
|---|---|---|---|---|---|
| **Name of The Course** | **Nutritional Assessment And Surveillance** | | | | |
| **Course Code** | **BNDT5002** | | | | |
| **Prerequisite** | | | | | |
| **Corequisite** | | | | | |
| **Antirequisite** | | | | | |
| | **L** | **T** | **P** | **C** | |
| | **3** | **0** | **0** | **3** | |

**Course Objectives:**

This course deals with nutritional assessment and surveillance

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Objective and importance of nutritional assessment |
| CO2 | Need and importance of rapid assessment procedures |
| CO3 | Uses, meaning of reference curve and growth chart |
| CO4 | Need and importance of diet surveys quality |

| | |
|---|---|
| CO5 | growth charts for various age groups |
| CO6 | Importance of nutrition and clinic |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| **Unit-1: Nutritional Status Assessment and Surveillance** **7 hours** |
| Meaning, need, objectives and importance. Community, regional, national and international surveillance systems. |
| **Unit-2: Rapid Assessment Procedures** **7 hours** |
| Need, importance, techniques, interpretation and steps in RAP.<br>Sources of secondary health data - sources of relevant vital statistics, importance of infant, child, maternal mortality rates, and epidemiology of nutrition related disease. |
| **Unit-3: Growth Chart** **7 hours** |
| Meaning, WHO Chart, and charts used in India, uses, meaning of reference curve and growth curve. |
| **Unit-4 : Nutritional Assessment** **7 hours** |
| Diet Surveys: need, importance, methods, interpretation, concept of conception unit, intra inter individual distribution in the family, verifying the adequacy of the diet with respect to RDA, concept of family food security. Clinical signs, biochemical and biophysical methods: need, importance, identifying signs of deficiency diseases, interpretation of the clinical signs, biochemical and biophysical values in major diseases. |
| **Unit-5: Growth Charts for Various Age Groups** **7 hours** |
| Anthropometry: Need, importance, standards for reference, techniques of measuring height, weight, head circumference, chest circumference, mid-arm circumference, skin fold thickness, waist hip ratio, calculation of BMI, interpretation of the measurements, use of growth charts for various age groups. |
| **Unit-6: Nutrition and Diet Clinic** **5 hours** |
| Nutritional losses, nutritional gains, changes in the physical, chemical properties and organoleptic qualities of foods due to processing. |

**Suggested Readings**


1. Jelliffe D, (1996): Assessment of Nutritional Status on the Community – WHO Monograph, Series No.53, Geneva.
2. Gupta P and Thakhar R, (2003): Nutritional Disorder and Community Health, Pointer Publishers, Jaipur.
3. Dr. Swaminathan.M, Food and Nutrition, 2nd Edition 1985, Reprint 2006. The Bangalore Printing and Publishing.
4. Whitney,E.N. and Rolfes, S.R Understanding Nutrition, 10th edition 2005 Thomson/Wadsworth Publishing company, Belmount. CA
5. Williams, R.Medications and older adults 2002.FDA Consumer magazine.


| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | **Nutritional care in disease condition** | | | | |
| Course Code | **BNDT5003** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

**Course Objectives**:
Students will get exposure about the nutritional care in specific disease condition and additional nutritional support system.

**Course Outcomes**

| | |
|---|---|
| CO1 | Nutritional management in infection and fever |
| CO2 | Nutritional support systems |
| CO3 | Nutritional management of physiological stress |
| CO4 | Nutritional management of GI diseases |
| CO5 | Nutritional Management in diseases of the liver, Pancreas and Biliary system |
| CO6 | Nutritional Management in critical care |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| **Unit-1: Nutritional management in infection and fever 7 Hrs** |
| Defense mechanism, Metabolic changes during infection, Classification and entity of fever infection, Typhoid/ TB / parasitic infestation/ Aids |
| **Unit-2: Nutritional support systems: 7 Hrs** |
| Enteral Nutrition- Site, Size of the tube, Feed-types, Complications<br>Parenteral Nutrition- Type, Composition, Complications<br>Obesity and underweight diet management, Nutritional management of eating disorders |
| **Unit-3: Nutritional management of physiological stress 7 Hrs** |
| Nutrition in wound healing, Surgery: Pre and post surgical dietary management,<br>Burns- Classification, Complication, Dietary management, Trauma: Dietary management, Sepsis: Dietary management |
| **Unit-4: Nutritional management of GI diseases 7 Hrs** |
| Esophagitis(GERD), Dyspepsia, Peptic ulcer, Gastritis, Gastrectomy: Dumping syndrome<br>Flatulence, Diarrhea, Constipation, Hemorrhoids, Diverticular disease, Duodenal ulcer, Inflammatory Diseases of Bowl: Crohn's disease and ulcerative colitis, Irritable bowl syndrome, Colostomy, Ileostomy<br>Malabsorption syndrome- Celiac disease (Tropical sprue), Steatorrhoea, Intestinal Brush border diseases<br>Protein losing enteropathy |
| **Unit-5: Nutritional Management in diseases of the liver, Pancreas and Biliary system 7 Hrs** |
| Progression of liver disease, Metabolic and nutritional Implications, Role of specific nutrients and alcohol in liver diseases. Nutritional care in liver disease in the context of results of specific liver function tests. Viral hepatitis, cirrhosis of Liver, Hepatic encephalopathy, Wilsons disease. Liver transplant<br>Biliary dyskinesia, Cholelithiasis, Cholecystitis, Cholecystectomy, Pancreatitis, Zollinger Ellison syndrome |
| **Unit-6: Nutritional Management in critical care 5 hours** |
| Nutritional screening and nutritional Status assessment of critically ill, Nutritional requirement according to the critical condition |

**Suggested Readings:**
1. Davidson's Human Nutrition – Geissler.

2. Nutrition and Biochemistry for Nurses by Jacob Anthikad
3. Willims S. R.: Essentials of Nutrition and Diet Therapy, 4th ed., Mosby College Pub. S. Louis, 1986. 4. Thomas, B.: Manual of Dietetic Practice, 1996.
4. L. MatareseGottschlich Contemporary Nutrition Support Practice, Saunders 1998
5. ASPEN; Nutrition Support, Dietetics

| **Name of The Course** | **Fundamentals of Clinical Research** | | | |
|---|---|---|---|---|
| **Course Code** | **BNDT5004** | | | |
| **Prerequisite** | | | | |
| **Co-requisite** | | | | |
| **Anti-requisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | 3 | 0 | 0 | 3 |

**Course Objectives**

Students will be exposed to Clinical Research and their requirements, Pharmaceutical Industry, Bioavailability and Bioequivalence Studies.

**Course Outcomes**

| | |
|---|---|
| **CO1** | Historical Aspects of clinical research, clinical research terminologies |
| **CO2** | Phases of Clinical Trial and Types of Clinical Trial including Virtual Clinical Trials |
| **CO3** | Responsibility, Composition and basic function of Instituitional Ethics Committee, NABH accreditation process |
| **CO4** | General ethical consideration |
| **CO5** | National and International clinical trials guideline |
| **CO6** | Analysis of Evidence-based medicine |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term Exam (MTE)** | **End Term Exam (ETE)** | **Total Marks** |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| **Unit I: Basic Introduction to Clinical Research** | **7 Hours** |
|---|---|
| Overview, Opportunities & Career options in Clinical Research, Glossary of GCP. Historical Aspects of clinical research, Brief description of different phases, Stakeholders in clinical research, Need/Area for clinical research. | |
| **Unit-2 Phases and Types of Clinical Trials** | **7 Hours** |
| Introduction to Clinical Trials – Phases of Clinical Trials, Types of Clinical Trials, Randomized/Non randomized Clinical Trial, Virtual-clinical trials, Drug discovery and development. | |
| **Unit-3: Operation of IRB/IEC** | **7 hours** |
| Introduction, Defining Scope of IRB/IEC, Responsibilities, Composition of IRB/IEC, Basic Functions, NABH Accreditation of EC, EC role in Special Population Studies. | |
| **Unit-4: General ethical Consideration** | **7 hours** |

| |
|---|
| Ethical review procedures, Informed consent process, Vulnerability, Clinical trials of drugs and other interventions, Assisted reproductive technology |
| **Unit-5: Introduction to Indian GCP, ICHGCP and ICMR 7 Hours** |
| Indian- good clinical practice, ICH-GCP E6, Overview of ICMR |
| **Unit-6: Evidence-based medicine 5 Hours** |
| Need for evidence based approach in making decisions in family medicine; difference between evidence based medicine and evidence based health care; classification of evidence – information levels; 5 steps process for use of evidence oriented approach in family medicine |

**Suggested Reading**


12. Indian GCP Guideline.
13. NDCT 2019
14. Design and Analysis of Clinical Trials: Concepts and Methodologies, 3rd Edition. SheinChung Chow, Jen-Pei Liu. Publisher: Wiley.
15. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Publisher: Wiley-Blackwell
16. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., Dupin-Spriet T., Simon P. Publisher: Karger


| **Name of The Course** | **Hospital and Healthcare Administration** | | | | |
|---|---|---|---|---|---|
| **Course Code** | **BNDT5005** | | | | |
| **Prerequisite** | | | | | |
| **Corequisite** | | | | | |
| **Antirequisite** | | | | | |
| | **L** | **T** | **P** | **C** | |
| | **3** | **0** | **0** | **3** | |

**Course Objectives:**

The students will be familiarized with to know about Indian healthcare system: The Indian healthcare sector is expanding rapidly, with an estimated market value of US$ 280 billion by 2020.
This course will provide strategic insights and business skills for those working across the worldwide health sector.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Basic concepts of Health, Natural history of disease and role of hospitals to offer various levels of care |
| CO2 | Introduction to Hospital Management, Concepts of Healthcare industry, Department and organization structure of different types of hospitals |
| CO3 | Hospital's Department, Supportive and Ancillary service Departments |
| CO4 | Basics of Drug Management, Computerized Drug management system |
| CO5 | Procurement of Drugs, Procedure of drug indenting |
| CO6 | Analyze the Health Systems in India |

**Continuous Assessment Pattern**

| **Internal Assessment (IA)** | **Mid Term Test (MTE)** | **End Term Test (ETE)** | **Total Marks** |
|---|---|---|---|
| **20** | **30** | **50** | **100** |

**Course Content**

| | |
|---|---|
| **Unit-1: Basic Concepts of Health** | **7 hours** |
| Concept of health & disease and well-being, Prevention aspect of diseases, Dynamics of disease transmission, Changing pattern of diseases, Common pathological conditions, Basic concepts of interpretation of investigations reports | |
| **Unit-2: Introduction to Hospital Management** | **7 hours** |
| Concepts of Healthcare industry and its ever-changing character, terminal planning, design and operation, Concept of hospitals, space required for separate functions, overview, design & planning of different types of hospitals, Problems and constraints in hospitals. | |
| **Unit-3: Deparmentation in Hospital** | **6 hours** |
| Organization, Structure, Vertical and Horizontal, Clinical and Non- Clinical, Supportive and Ancillary service Departments, Department and organization structure of different types of hospitals. | |
| **Unit-4 : Basics of Drug Management** | **7 hours** |
| Drug Management, Hospital Pharmacy License and Drug License, Narcotics drug storage, Pharmacy billings, Computerized Drug management system, Rational use of Drugs and Prescription Audits, Spurious Drugs, Banned Drugs | |
| **Unit-5: Procurement of Drugs** | **6 hours** |
| Purchase of drugs and other consumable materials, Procedure of drug indenting, On time drug dispensing inventory control, Methods of ordering – two bin system (lead time, buffer stock, reorder level) cyclic system | |
| Unit-6 **Health Systems in India** | **7 hours** |
| Health planning in India including various committees and National Health Policy and Health Goals set from time to time. Organised sector with reference to Centre, State, District and Block level structures and local bodies and Panchayati Raj Organisation and functions of community health centres and Primary Health Centres (PHCs). Health Manpower, Primary Health care and concept, Alternative systems of medicine, like Ayurveda, Homeopathy, etc. Holistic Approach Non-Governmental Organisations (NGOs) and Private Voluntary Organisations (PVOs). Unorganized Sector | |

**Suggested Readings:**


1. Hospital Management: Principle, Theory and Practice by Amit Virmani
2. Hospital Management: An Evaluation – by A.K. Malhotra
3. Principles of Hospital Administration & Planning: B.M. Sakharkar (Jaypee)


| | | | | | |
|---|---|---|---|---|---|
| **Name of The Course** | **PHARMACOLOGY II** | | | | |
| **Course Code** | **BNDT5006** | | | | |
| **Prerequisite** | | | | | |
| **Corequisite** | | | | | |
| **Antirequisite** | | | | | |
| | **L** | **T** | **P** | **C** | |
| | **3** | **0** | **0** | **3** | |

**Course Objectives:**

The basic objective of this course is to get familiar with pharmacology.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Understand the different drugs acting on central nervous system |
| CO2 | Understand the different drugs acting on autonomic nervous system |
| CO3 | Understand the different drugs acting on cardiovascular system |
| CO4 | Understand the Anti-hypertensive drugs and their mechanism of action |
| CO5 | Understand the Drugs acting on respiratory system |

| | |
|---|---|
| CO6 | Analyzing the drugs acting on Blood |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| **Unit-1: Drugs acting Central Nervous System(CNS) 7 hours** |
| General anesthetics, anxiolytics and hypnotics drugs, anti depressants, CNS stimulants and psychotomimetic drugs, Opioid analgesics and opioid anatagonists, Drug dependence and drug abuse, Antiepileptic drugs, Drug therapy for neurodegenerative disorders like parkinson's disease and schizophrenia. |
| **Unit-2: Drugs acting on Autonomic Nervous System (ANS) 7 hours** |
| General introduction, Parasympathomimetic, parasympatholytic, Sympathomimetic, sympatholytic agents, Ganglionic stimulants, blockers and adrenergic neuron blocking drugs, local anesthetics |
| **Unit-3: Drugs acting on Cardiovascular System (CVS) 7 hours** |
| Cardiac glycosides and positive ionotropic agents, Anti-arrhythmic drugs, Antihypertensive drugs, Coronary vasodilators and drugs used in angina, Anti-hyperlipidemic drugs, Fibrinolytic agents, Cardioprotective agents, Anti-anginal agents. |
| **Unit-4: Antihypertensives: 7 hours** |
| Overview, classification of antihypertensive drugs- Diuretics, Sympatholytics, angiotensin inhibitors, vasodilator, dopamine agonists |
| **Unit-5: Drugs acting on Respiratory System and NSAID 7 hours** |
| Expectorants, Anti-tussive bronchodilators, Drugs used in common cold. Classification of NSAIDS, Mechanism of action, NSAIDSwhich do not inhibit prostaglandin synthesis. |
| **Unit-6: Drugs Acting on Blood 5 hours** |
| Agents used to treat anemias and haematopoietic growth factors; Coagulants and anticoagulants; Antiplatelet drugs; Fibrinolytic, antifibrinolytic, plasma expanders |

**Suggested Readings**

**1.** Tripathi, K.D., Essentials of Medical Pharmacology, Jay Pee Publishers, New Delhi.
2. Satoskar & Bhandarkar, Pharmacology & Pharmacotherapeutics, Popular Prakashan Pvt. Ltd.,Bombay.
3. Katzung, B.G., Basic & Clinical Pharmacology, Prentice Hall, International.
4. Rang M.P., Dale M.M., Riter J.M., Pharmacology, Churchill Livingstone.
5. Barar F.S.K., Text Book of Pharmacology, Interprint, New Delhi.
6. Kulkarni S.K., Hand Book of Experimental Pharmacology, Vallabh Prakashan, Delhi.

# Semester VI

| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | **Project and Dissertation** | | | | |
| Course Code | **BNDP6051** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 0 | 0 | 30 | 15 |

**Course Objectives:**

Students will get exposure of Project work execution in the area of Nutrition and Dietetics.

**Course Outcomes:**

On completion of this course the students will be able to

| | |
|---|---|
| CO1 | Formulate questions and to discover feasible solutions |
| CO2 | Demonstrate individual initiative or group responsibility |
| CO3 | Use resource materials to express ideas and talents |
| CO4 | Design and execute the project work |
| CO5 | Report the project work in terms of thesis |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **60** | **00** | **240** | **300** |

**Course Content**

**Unit-1: Project and dissertation** **9 hours**

This project work is to make the student acquainted with the Patient/Healthcare sector/ industrial/ Sports person. After completion of the project they will have to submit dissertation report

This project work or thesis presents a student's research results, describing the research with reference to relevant work done as part of the live project at a Hospital/Healthcare sector/Patients with specific diseases and sports person.

It will include a description of the methods of research considered, and those actually employed, and present the student's conclusions. The thesis is the student's own work and must be written by the student.

The Internal Layout of the project work or Thesis

The thesis is to be submitted in the following pattern,

- Title page;
- Summary (Abstract)
- Table of contents
- List of tables
- List of figures
- Definitions or Abbreviations;
- Declarations and Statements
- Acknowledgement
- Author's declaration
- Contents page;
- Introduction
- Study Objectives
- Subject selection and withdrawal
- Study nutrition/management
- Statistical Plan
- Safety and adverse event's
- Glossary
- List of references
- Bibliography
- Index

GALGOTIAS UNIVERSITY

(Established under Galgotias University Uttar Pradesh Act No. 14 of 2011)

# Program: M.Sc. Nutrition and Dietetics

**Scheme: 2020-2021**

**Vision:-** To be known globally for education, innovation and interdisciplinary research in Biosciences, Healthcare and Biomedical Engineering.

**Mission:**

**M1**. To establish the centre of excellence in Nutrition and Dietetics.

**M2**. To establish state-of-the-art facilities of Nutrition and Dietetics for world class education and research.

**M3**. To conduct the multidisciplinary research in collaboration with national and international organization for developing the innovative solutions of unsolved health problems.

**Program Educational Objectives:**

**PEO** 1. Graduates shall work as nutritionists and dieticians in various hospitals and health sectors to improve people's health

**PEO** 2. Graduates shall conduct research/ higher studies in Nutrition and Dietetics as well as in the interdisciplinary field to exhibit global competitiveness.

**PEO** 3. Graduates shall possess strong skills in Nutrition and Dietetics and are able to establish their own start-ups.

**Program Specific Objectives:**

**PSO**1. Evaluate critical domestic and global nutritional related issues that challenge and influence the Nutraceutical product development

**PSO**2. Demonstrate competencies in performing the research; evaluating, analysing and presenting the results.

**PSO**3. Effectively communicate and collaborate with health care providers and regulatory agencies to improve people's health and help them make better dietary choices

**PSO**4. Demonstrate regulations, social and ethical values required to make a global nutritional expert

**Program Outcomes:**

**PO**1- Nutrition and Dietetics Knowledge: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of nutrition and dietetics.

**PO**2- Planning Abilities: Demonstrate effective planning abilities including time management, resource management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

**PO**3- Problem analysis: Utilize the principles of Analytical thinking, clearly and critically, while solving problems and making decisions during handling patients, Sports person and making food chart for all age groups and also analyze, evaluate and apply information systematically and making decisions related to it.

**PO**4- Modern tool usage: Learn and apply modern and appropriate practical applicable toolsof a scientific understanding of nutrition.

**PO**5- Leadership skills: Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfillment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles during the conduction of their job to facilitate improvement in health and wellbeing.

**PO**6- Professional Identity: Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, Clinical Researcher, managers, employers, employees)

**PO**7- Nutrition and Dietetics Ethics: Honor human values and apply ethical principles in professional and social contexts. Demonstrate behavior that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions.

**PO**8- Communication: Communicate effectively with the Nutritional community (healthcare provider, doctor and patient and write effective reports, make effective presentations and documentation, and give and receive clear instructions.

**PO**9- The Nutrition and Dietetics and society: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the Nutritional practice.

**PO**10- Environment and sustainability: Understand the impact of the Nutritional solution in societal and environmental contexts, demonstrate the knowledge of, and need for sustainable development.

**PO**11- Life-long learning: Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self access and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

## Curriculum

| Semester 1 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sl. No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | MNAD1001 | Basic nutrition | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | MNAD1002 | Research Methodology and Biostatictics | 4 | 0 | 0 | 4 | 20 | 30 | 50 |
| 3 | MNAD1003 | Human Physiology-I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | | Disruptive technologies | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 5 | | Professional communication | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | | Environmental Studies | 0 | 0 | 1 | 0.5 | 50 | -- | 50 |
| 7 | | Campus to corporate | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 8 | | Ethics and Professional Competency | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 9 | | Creative / Liberal Arts | 0 | 0 | 1 | 0.5 | 50 | -- | 50 |
| 10 | | Waste management | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 11 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| | | **Total** | **21** | **0** | **2** | **22** | **280** | **270** | **550** |
| **Semester II** | | | | | | | | | |
| **Sl No** | **Course Codee** | **Name of the Course** | | | | | **Assessment Pattern** | | |
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| 1 | MNAD2001 | Nutritional care in disease condition-I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | MNAD2002 | Human Physiology-II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | MNAD2003 | Nutritional Biochemistry | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | MNAD2004 | Nutraceuticals and Functional Foods-I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | MNAD2005 | Nutritional Management-I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | MNAP2051 | Nutrition and dietetics Lab-I | 0 | 0 | 4 | 2 | 50 | -- | 50 |
| 7 | | Professional communication | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 8 | | Foreign Language | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| | | **Total** | **20** | **0** | **4** | **22** | **190** | **210** | **400** |
| **Semester III** | | | | | | | | | |
| **Sl No** | **Course Code** | **Name of the Course** | | | | | **Assessment Pattern** | | |
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| 1 | MNAD3001 | Therapeutic Nutrition | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | MNAD3002 | Nutritional care in disease condition-II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | MNAD3003 | Nutritional Management-II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | MNAD3004 | Community Nutrition | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | MNAD3005 | Nutraceuticals and Functional Foods-II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | MNAP3052 | Nutrition and dietetics Lab-II | 0 | 0 | 4 | 2 | 50 | -- | 50 |
| 7 | | Aptitude building and logical reasoning | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 8 | | Disaster Management | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| 9 | | AI and its application | 0 | 0 | 4 | 2 | 50 | -- | 50 |
| 10 | | Creativity, Innovation and entrepreneurship and IPR | 1 | 0 | 0 | 1 | 20 | 30 | 50 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | **Total** | **19** | **0** | **8** | **23** | **290** | **240** | **500** |

**Semester IV**

| **Sl No** | **Course Code** | **Name of the Course** | | | | | **Assessment Pattern** | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| 1 | MNAD4001 | Project and Dissertation | 0 | 0 | 26 | 13 | 60 | 00 | 240 |
| | | **Total** | **0** | **0** | **26** | **13** | **60** | **00** | **240** |

# Semester- I

| | | | | |
|---|---|---|---|---|
| **Name of The Course** | **Basic Nutrition** | | | |
| **Course Code** | **MNDT1001** | | | |
| **Prerequisite** | | | | |
| **Co-requisite** | | | | |
| **Anti-requisite** | | | | |
| | **L** | **T** | **P** | **C** |
| | 3 | 0 | 0 | 3 |

**Course Objectives**

1. Students will be exposed to basics of Nutrition and their requirements.

**Course Outcomes**

| | |
|---|---|
| **CO1** | Concepts and definitions of Nutrition |
| **CO2** | Energy Balance |
| **CO3** | function of carbohydrate |
| **CO4** | Definition, classification and function of Protein |
| **CO5** | Definition, classification and function of Lipids |
| **CO6** | Definition, classification and function of Vitamins and Minerals |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Exam (MTE) | End Term Exam (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| |
|---|
| **Unit I: Introduction to Nutrition** **7 Hours** |
| Concept and definition of terms Nutrition, Malnutrition and Health. Brief History of Nutritional Science, Scope of Nutrition. Minimal Nutritional Requirements and RDA- Formulation of RDA and Dietary Guidelines- Reference Man and Reference women. |
| **Unit-2 Energy Balance** **7 Hours** |
| Overview, Concept and Definition, Energy Balance, Assessment of Energy Requirements, Deficiency and Excess, Energy Chart flow, Energy Calculation |
| **Unit-3 Carbohydrates** **7 Hours** |
| Carbohydrates- Definition, Classification and functions. Digestion and Absorption, Blood glucose and effect of different carbohydrates on blood glucose. Dietary Fibre - Nutritional significance |
| **Unit-4: Protiens** **7 Hours** |

| |
|---|
| Definition, classification and functions. Assessment of protein quality (BV, PER, NPU), Digestion and Absorption, factors affecting protein bio-availability including anti-nutritional factors. Requirements, deficiency. |
| **Unit-5: Lipids** **7 Hours** |
| Definition, classification and functions of lipids. Digestion and absorption, Intestinal re-synthesis of triglycerides. Types of fatty acids, role and nutritional significance (SFA,MUFA,PUFA, omega-3). |
| **Unit-6: Minerals, Trace Elements And Vitamins** **5 Hours** |
| Minerals - Physiological role, bio-availability and requirements, sources, Deficiency and Excess(Calcium, Phosphorus, Magnesium, Iron, Fluoride, Zinc, Iodine)<br>Vitamins-Physiological role, Bio-availability and requirements, sources, deficiency and excess(Fat soluble and water soluble) |

**Suggested Reading**

3. Shubhangini A. Joshi,(1992)' "Nutrition and Dietetics"Tata Mc Grow- Hill publishing Company Ltd, New Delhi.
4. Srilakshmi. B – "Nutrition Science", V Edn, New Age International (P) Ltd, Publishers, Chennai
3. Passmone R.and Eastwood M.A,(1986), "Human Nutrition and Dietetics",English language book Society/Churchill Livingstone,Eigth edition, Hong Kong.
4. Neiman N. Catherine, (1990), "Nutrition",Wm.C. Brown Publishers. USA.

| **Name of The Course** | **Research Methodology & Biostatistics** | | | | |
|---|---|---|---|---|---|
| **Course Code** | **MNDT1002** | | | | |
| **Prerequisite** | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 4 | 0 | 0 | 4 |

**Course Objectives**:
Students will get exposure about Research Methodology

**Course Outcomes:**
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Research |
| CO2 | Understand about the Research Design |
| CO3 | Understand about the Research Report and ethics |
| CO4 | Understand about the Sampling methods |
| CO5 | Understand about the Measures of central tendency |
| CO6 | Understand about Hypothesis testing |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| | |
|---|---|
| **Unit-1: Introduction to Research** | 8 hours |
| Research definition, types, advantage and significance. Introduction to research methods, identifying research problem, definition, objectives, role, scope in biotech research, process of research, limitations & types | |
| **Unit-2: Research Design** | 7 hours |
| Concept of Interdisciplinary Research, Procedures in research. Types of Research Design: Experimental/Interventional research, Quasi-experimental studies, Observational research. Sources of Experimental Errors. Survey research: Types of surveys- CATI, CAPI, Mail, Email, Face-to-face, Questionnaire | |
| **Unit-3: Research Report and ethics** | 5 hours |
| Type of research report- Research, review, case report, manuscript, monograph, book chapters. Structure of Research Reports. Quoting of reference and bibliography using reference management tools. Ethical issues in research, plagiarism. | |
| **Unit-4: Sampling methods** | 5 hours |
| Sampling methods, Advantages and Limitation, Sampling process, Types of Sampling, Probability and Non Probability sampling techniques, sampling errors, Data collection Primary and secondary data, Collection and validation. | |
| **Unit-5: Measures of central tendency** | 8 hours |
| Measures of central tendency- Mean, Median, Mode; Measures of dispersion- Range, Mean deviation and Coefficient of variation, Standard deviation, Standard error; Correlation and regression; Statistical inference- Hypothesis testing, Significance level, Confidence interval, t-test, z-test. Test of significance for large and small samples; Parametric tests; Non parametric tests; Experimental design, Use of biostatistic softwares. | |
| **Unit-6: Hypothesis testing** | 7 hours |
| Null hypothesis and test of significance (t-test, paired t-test, Analysis of variance, Analysis of covariance, Coefficient of Variation, chi-square test, Fischer exact, Mann-Whitney, Wilcoxin, McNeman test, Kruskal Wallis. | |

**Suggested Readings**:


17. Graziano AM, Raulin ML. Research methods: A process of inquiry. HarperCollins College Publishers; 1993.
18. C.R. Kothari : Research Methodology, New Age International Publishers
19. Bouma GD, Ling R, Wilkinson L. The research process. Oxford: Oxford University Press; 1993 Mar 30.
20. Dawson B, Trapp RG. Basic and clinical biostatistics. Singapore. 2004;2001:141-2.


| | | | | | |
|---|---|---|---|---|---|
| **Name of The Course** | **Human Physiology-I** | | | | |
| **Course Code** | **MNDT1003** | | | | |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50 % marks in aggregate | | | | |
| Corequisite | Basic knowledge of physiology. | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

**Course Objectives:** Students are able to understand the basic concept of Physiology and they can apply the knowledge of physiology in understanding the various .diseases and keeping the body in healthy state.

**Course Outcomes**

| | |
|---|---|
| CO1 | Understand the Digestive system. |
| CO2 | Interpret the composition of blood and its function circulatory system of human |
| CO3 | Interpret the circulatory system in human |
| CO4 | Evaluate the respiratory system |
| CO5 | Understand the excretory system. |

| | |
|---|---|
| CO6 | Analyze the Male Reproductive system |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| | |
|---|---|
| **Unit-1 Digestive system** | **7 Hours** |
| Digestive system – Homeostasis, structure of stomach and intestine, Digestive gland and Hormones, Digestion of food in different parts of alimentary canal, absorption and assimilation. | |
| **Unit-2 Blood and circulation** | **7 Hours** |
| Blood and circulation - Blood corpuscles, hemopoieses and formed elements, plasma function, blood volume, WBC and platelets function. Anemia, thalassemia, Leukemia, Polycythemia, Hemostasis and blood coagulation mechanism, blood groups and blood banking. hematocrits value | |
| **Unit-3 Cardiovascular System** | **7 Hours** |
| Cardiovascular System: Comparative anatomy of heart structure, myogenic heart, specialized tissue, ECG – its principle and significance, cardiac cycle, heart as a pump, blood pressure, neural and chemical regulation. | |
| **Unit-4 Respiratory system** | **7 Hours** |
| Respiratory system – structure of lungs and surfactant function, Mechanism of breathing, anatomical considerations, alveolar ventilation, vital capacity of lungs, transport of gases, exchange of gases, waste elimination, neural and chemical regulation of respiration. | |
| **Unit-5 Excretory system** | **7 Hours** |
| Excretory system - Comparative physiology of excretion, kidney, urine formation, urine concentration, waste elimination, micturition, regulation of water balance, blood volume, blood pressure, electrolyte balance, acid-base balance. | |
| **Unit-6: Male Reproductive system** | **5 Hours** |
| Testis, Duct system, Functions. Semen-secretion, composition, Oligozoospermia. | |

**Suggested Readings**


10. Guyton A.C, Hall J.E, Textbook of Medical Physiology, 11th Ed., Saunders Company, 2005.
11. Widmaier E. P, Raff H, Strang K. T. Vander's, Human Physiology : The mechanism of Body Function, 9th Ed. Mc. Graw Hill, 2003.
12. Ganong W. E, Review of Medical Physiology, 21st Ed., Mc. Graw Hill, 2003.


# Semester-II

| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | **Nutritional care in disease condition-I** | | | | |
| Course Code | **MNAD2001** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

**Course Objectives:**

Students will get exposure about the nutritional care in physical fitness, gene expression and diet modification therapy.

**Course Outcomes:**

After completion of this course work students able to

| | |
|---|---|
| CO1 | Geriatric population |
| CO2 | Sport Nutrition and Physical fitness |
| CO3 | Nutritional requirements for extreme environments |
| CO4 | Nutritional regulation of Gene Expression, Epigenetic & Nutrigenomics |
| CO5 | Nutrigenomics |
| CO6 | Medical Nutrition and Diet Modification therapy |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**:

| | |
|---|---|
| **Unit-1: Geriatric population** | 7 hours |
| Definition of old age, Nutrition and ageing, Physiological changes associated with ageing, Changing body composition and techniques for measuring body composition. Nutritional requirements and dietary modification in the diet of the elderly Guidelines for planning balanced diet for elderly | |
| **Unit-2: Sport Nutrition and Physical fitness** | 7 hours |
| Introduction, Evaluation and growth of sports nutrition as a discipline, Anthropometric and physiological measurement. Various techniques for measuring body composition. Work capacity | |
| **Unit-3: Nutritional requirements for extreme environments** | 5 hours |
| General adaptive mechanisms to environmental extreme and role of nutrition in successful acclimatization, Health Hazards associated with high altitude, Nutritional requirements in high altitude Nutritional requirements in high cold and polar envelopment, Nutritional requirements in hot environments, Nutritional requirements for space missions | |
| **Unit-4: Nutritional regulation of Gene Expression, Epigenetic** | 7 hours |
| Introduction, Gene – Expression- An overview, Role of specific nutrients in controlling gene expression, Proteins, Lipids, Minerals, Vitamins | |
| **Unit-5: Nutrigenomics** | 7 hours |
| Immunonutrition- Role of specific nutrients in immune suppression. Role of nutrients in immune promotion Functional foods and nutriacuticles in health disease, History, Definition, Classification, Physiological effects, effects of human health and potential applications in risk reduction of diseases | |
| **Unit-6: Medical Nutrition and Diet Modification therapy** | 7 hours |
| Definition, Nutritional screening, Nutritional care process, Nutritional Assessment, Nutritional diagnosis, Nutritional Intervention, Monitoring and evaluation<br>Adequate normal diet as basis for therapeutic diets, Diet prescription, Modification of normal diet. Nomenclature of diet adequacy in standard hospital diet. Psychological factors in feeding the sick person. Interaction among drugs, food nutrients and nutritional status, Effects of drugs on food intake nutrient absorption, Metabolism and requirements. Drugs affecting intake of food and nutrients Absorption Metabolism and excretion Nutritional status, Effect of food, nutrients and nutritional status on absorption and metabolism of drugs | |

**Suggested Readings**:

1. International Life Sciences Institute Present Knowledge in Nutrition – latest edition

2. Swaminathan S.: Advanced Textbook On Food & Nutrition Vol. 1 & N (2nd Ed. Revised Enlarged) Bapp Co. 1985.

3. Robinson. Basic Nutrition And Diet Therapy (8th Edition)

4. Robinson, Lawler: Normal & Therapeutic Nutrition (17th Ed.) Macmillan Publishing Co. 1986.
5. Davis J. and Sherer, K. (1994): Applied Nutrition and Diet Therapy for Nurses, 2nd edition, W.B. Saunders Co.
6. Davidson's Human Nutrition – Geissler

| | | | | |
|---|---|---|---|---|
| **Name of The** | **HUMAN PHYSIOLOGY-II** | | | |
| **Course Code** | **MNAD2002** | | | |
| Prerequisite | Higher Secondary Examination with Chemistry and Biology or Chemistry, Botany and Zoology or Biochemistry and Chemistry from a recognized Board in science stream with a minimum of 50 % marks in aggregate. | | | |
| Corequisite | Basic knowledge of human physiology | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**: Students are able to understand the basic concept of Physiology and they can apply the knowledge of physiology in understanding the various diseases and keeping the body in healthy state.

**Course Outcomes**

Students are able to

| | |
|---|---|
| CO1 | Describe Structure of Neurons, action potential, Neurotransmitter |
| CO2 | Explain Mechanism of Muscle contraction in skeletal tissue |
| CO3 | Describe Structure and functional anatomy of eye and ear |
| CO4 | Explains Endocrinology including hormones and their action |
| CO5 | Explain Reproductive processes |
| CO6 | Understand the Skeletal physiology |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| |
|---|
| **Unit-1 Nervous system** **7 hours** |
| Nervous system: Structure of Neurons, action potential, Neurotransmitter, gross neuroanatomy of the brain and spinal cord, central and peripheral nervous system, Structure of cerebrum and function of different area of cerebral cortex, memory and cognition, Thermoregulation, mechanism of thermo sensation pathways. |
| **Unit-2 Muscle physiology** **7 hours** |
| Muscle physiology: Mechanism of Muscle contraction in skeletal tissue, structural and function difference between skeletal muscle and cardiac muscle. Structure of actin and myosin filament, Tetany, muscular dystrophy. |
| **Unit-3 Sensory system** **7 hours** |
| Sensory system: Functional anatomy of eye, Structure and functional anatomy of retina, Structure of rod and cone cells and their pigments, Molecular mechanism of rhodopsin, mechanism of Vision, hyperpolarization of rod receptor potential, Functional anatomy of ear; structure and function of organ of corti, Inner hair cells (IHC) and |

| |
|---|
| outer hair cells (OHC) stereocilia, mechanism of Hearing. Common disorders of the following sensations: Vision, Hearing, Taste, Smell and Touch |
| **Unit-4 Endocrine System** **7 hours** |
| Endocrinology: Endocrine glands: Pituitary gland and hormone, thyroid gland and its hormone, adrenal gland and its hormone function, basic mechanism of hormone action, hormones and diseases. |
| **Unit-5 Female Reproductive system** **7 hours** |
| Reproductive system: Reproductive processes, gametogenesis, ovulation, neuroendocrine regulation, Menstrual cycle, Hormones related to ovulation and reproductive cycle. |
| **Unit-6 Skeletal physiology** **5 hours** |
| Cartilage – types with example & histology, Bone – Classification, names of bone cells, parts of long bone, microscopy of compact bone, names of bones, vertebral column, fontanelles of fetal skull, Joints – Classification with examples |

**Suggested Readings:**


10. Guyton A.C, Hall J.E, Textbook of Medical Physiology, 11th Ed., Saunders Company, 2005.
11. Widmaier E. P, Raff H, Strang K. T. Vander's, Human Physiology : The mechanism of Body Function, 9th Ed. Mc. Graw Hill, 2003.
12. Ganong W. E, Review of Medical Physiology, 21st Ed., Mc. Graw Hill, 2003.


| | | | | |
|---|---|---|---|---|
| Name of The Course | **Nutritional Biochemistry** | | | |
| Course Code | **MNAD2003** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:

Students will get exposure about the metabolism of biomolecules

**Course Outcomes**

| | |
|---|---|
| CO1 | Metabolism of carbohydrates |
| CO2 | Amino acid metabolism |
| CO3 | Lipid metabolism |
| CO4 | Nucleotide metabolism and molecular biology |
| CO5 | Enzymology |
| CO6 | Minerals |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| **Unit-1: METABOLISM OF CARBOHYDRATES** **7 Hrs** |
| Review of glycolysis, fate of pyruvate: alcoholic and homolactic fermentation, Cori cycle, Citric acid cycle. Hexose monophosphate shunt, glycogenesis, glycogenolysis, gluconeogenesis, glyoxalate cycle. Regulation of blood glucose level.<br>Major alterations in carbohydrates, protein and fat metabolism in chronic nutrition related degenerative diseases. |
| **Unit-2: AMINO ACID METABOLISM** **7 Hrs** |

| |
|---|
| Transamination, deamination, urea cycle, amino acids as biosynthetic precursors- biosynthesis of heme, biologically active amines and glutathione.<br>Electron transport chain (ETC): elucidation,components and operation, oxidative phosphorylation and its mechanism, P/O and P/H ratio, uncouplers |
| **Unit-3: LIPID METABOLISM 7 Hrs** |
| Beta-oxidation of saturated and unsaturated fatty acids (including brief account of minor pathways of fatty acid oxidation), biosynthesis of fatty acids, triacylglycerols, Phospholipids, ketone body formation and their utilization, prostaglandins. |
| **Unit-4: NUCLEOTIDE METABOLISM AND MOLECULAR BIOLOGY 7 Hrs** |
| Biosynthesis of purines and pyrimidines, DNA replication, transcription, translation, regulation of gene expression (Prokaryotes), mutagenesis and DNA repair, recombinant DNA technology and genetically modified foods. |
| **Unit-5: ENZYMOLOGY 7 Hrs** |
| Mechanism of enzyme action (acid base catalysis, covalent catalysis, metal ion catalysis, electrostatic catalysis, proximity and orientation effect, preferential binding of the transition stae complex, strain and distortion theory) Enzyme inhibition – irreversible(non-competitive,uncompetitive), reversible(competitive), feed back and product inhibition, regulation of enzyme activity by covalent modification, allosteric modification, isoenzymes, applications of enzymes in medicine and food industry |
| **Unit-3: Minerals 5 Hrs** |
| Macro minerals: calcium, phosphorus, magnesium sodium, potassium and chloride. Micro minerals: Iron, copper, zinc, manganese, iodine, fluoride. Trace minerals: Selenium, cobalt, chromium, vanadium, silicon, boron, nickel.<br>(Note: For each nutrient sources, bioavailability, function requirements, RDI/ESADDI, deficiency and toxicity, interactions with other nutrients are to be discussed) |

**Suggested Readings:**

1. Harper's Biochemistry- Robert K. Murray
2 Textbook of Biochemistry- West and Todd
3 Bio chemical aspect of Nutrition – S.X.C. - Okoyo
4 Food Chemistry – O.R. Fennema
5 Biochemistry – Voet and Voct
6 Principles of Biochemistry – A.L. Lehniger
7. Outlines of Biochemistry- E. E. Conn
8. Practical Clinical Biochemistry- Harold Varley

| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | **Nutraceuticals and Functional Foods-I** | | | | |
| Course Code | **MNAD2004** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

**Course Objectives:**
Students will get exposure about the neutraceutical and functional food in different disease condition.

**Course Outcomes**

| | |
|---|---|
| CO1 | Basics of Nutraceuticals as Science |
| CO2 | Properties, structure and functions of various Nutraceuticals |
| CO3 | Food as remedies |
| CO4 | Anti-nutritional Factors present in Foods |
| CO5 | Development of Novel Food and food Ingredients: Polysaccharides, low caloric sweeteners |
| CO6 | Nutraceutical industries in India and abroad |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| **Unit 1 Introduction to Nutraceuticals as Science 7 Hrs** |
| Historical perspective, classification, scope & future prospects. Applied aspects of the Nutraceutical Science. Sources of Nutraceuticals. Relation of Nutraceutical Science with other Sciences: Medicine, Human physiology, genetics, food technology, chemistry and nutrition. |
| **Unit 2: Properties, structure and functions of various Nutraceuticals 7 Hrs** |
| Glucosamine, Octacosanol, Lycopene, Carnitine, Melatonin and Ornithine alpha ketoglutarate. Use of proanthocyanidins, grape products, flaxseed oil as Nutraceuticals. |
| **Unit 3: Food as remedies 7 Hrs** |
| Nutraceuticals bridging the gap between food and drug, Nutraceuticals in treatment for cognitive decline, Nutraceutical remedies for common disorders like Arthritis, Bronchitis, circulatory problems, hypoglycemia, Nephrological disorders, Liver disorders, Osteoporosis, Psoriasis and Ulcers etc. Brief idea about some Nutraceutical rich supplements e.g. Bee pollen, Caffeine, Green tea, Lecithin, Mushroom extract, Chlorophyll, Kelp and Spirulina etc. |
| **Unit 4: Anti-nutritional Factors present in Foods 7 Hrs** |
| Types of inhibitors present in various foods and how they can be inactivated. General idea about role of Probiotics and Prebiotics as nutraceuticals. Recent advances in techniques & feeding of substrates. Assessment of nutritional status and Recommended Daily allowances. |
| **Unit 5: Development of Novel Food and food Ingredients: Polysaccharides, low caloric sweeteners 7 Hrs** |
| Naturally produced flavor modifiers, Single Cell Proteins, Marine algae as food supplements, Food supplements and food Ingredients as byproducts – Fishery, poultry/animal husbandry and agriculture/dairy industries. |
| **Unit 6: Nutraceutical industries in India and abroad 5 Hrs** |
| Reputed Indian and International industries involved in production and development of Nutraceuticals and functional foods |

**Suggested Readings:**

1) Nutraceuticals: Efficacy, Safety and Toxicity by Ramesh C. Gupta
2) Nutraceuticals: The Complete Encyclopedia of Supplements, Herbs, Vitamins and Healing Foods by Arthur J. Roberts, Genelle Subak-Sharpe, et al.
3) Advances in Nutraceutical Applications in Cancer: Recent Research Trends and Clinical Applications (Nutraceuticals) by Sheeba Varghese Gupta and Yashwant V Pathak
4) Nutraceuticals in Health and Disease Prevention (Infectious Disease and Therapy Book 6) by PETER. PAUL HOPPE, Klaus Kramer, et al.

5) Nutrigenomics and Nutraceuticals: Clinical Relevance and Disease Prevention by Yashwant V. Pathak and Ali M. Ardekani
6) Pharmaceuticals to Nutraceuticals: A Shift in Disease Prevention by Dilip Ghosh and R. B. Smarta
7) Handbook of Nutraceuticals and Functional Foods (Modern Nutrition) by Robert E.C. Wildman and Richard S. Bruno

| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | **Nutritional Management-I** | | | | |
| Course Code | **MNAD2005** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

**Course Objectives:**
Students will get exposure about the nutritional management in different disease condition.

**Course Outcomes**

| | |
|---|---|
| CO1 | Basics of Nutritional management in coronary heart disease |
| CO2 | Nutrition Management of Renal Disease |
| CO3 | Nutritional management in cancer |
| CO4 | Nutrition management in Diseases of nervous system and musculoskeletal system |
| CO5 | Etiology dietary treatment in arthritis and osteoporosis |
| CO6 | Nutritional management in coronary heart disease |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| **Unit-1: Basics of Nutritional management in coronary heart disease 7 Hrs** |
| Pathogenesis, role of nutrients in prevention and management, Nutritional and metabolic implications of dyslipidemias. |
| **Unit-2: Nutrition Management of Renal Disease 7 Hrs** |
| Diseases of renal system: etiology and pathogenesis: change in function with progression of diseases, metabolic and nutritional implications. Clinical and metabolic manifestations, Diagnostic tests<br>Types - Acute and chronic nephritis, Nephrotic syndrome, Renal Failure: Acute and chronic, ESRD |
| **Unit-3: Nutritional management in cancer 7 Hrs** |
| Cancer: Pathogenesis and progression of cancer Role of Nutrients and food additives in cancer therapies and their nutritional implications. Types - Symptoms, Diagnosis, Cancer therapies: Nutritional implications, Dietary management |
| **Unit-4: Nutrition management in Diseases of nervous system and musculoskeletal system 7 Hrs** |
| Dysphagia, Epilepsy, Hyperkinetic behavior syndrome, Neurodegenerative disorders |
| **Unit-5: Etiology dietary treatment in arthritis and osteoporosis 7 Hrs** |
| Definition, symptoms mechanism of food allergy, Biochemical and immune testing (Brief), Elimination diets, Food selection, Food allergy in infancy: Milk sensitive enteropathy, intolerance to breast milk. Prevention of food allergy |

| **Unit-6: Nutritional management in coronary heart disease** | **5 hours** |
|---|---|
| CHD - Prevalence, Etiology and risk factors, Diagnostic tests, Nutrition management<br>Common disorders of CHD and Nutrition management - Dyslipidemias, Atherosclerosis, Hypertension, IHD, CCF, Rheumatic heart disease | |

**Suggested Readings:**

1. Willims S. R.: Essentials of Nutrition and Diet Therapy, 4th ed., Mosby College Pub. S. Louis, 1986.
2. Thomas, B.: Manual of Dietetic Practice, 1996.
3. L. MatareseGottschlich Contemporary Nutrition Support Practice, Saunders 1998
4. ASPEN; Nutrition Support, Dietetics
5. Clinical dietetics and nutrition by F.P Antia and Philip Antia.

# Semester-III

| Name of The Course | **Therapeutic Nutrition** | | | |
|---|---|---|---|---|
| Course Code | **MNAD3001** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**
Students will get exposure about the therapeutic nutrition, modification and dietary management.

**Course Outcomes**

| | |
|---|---|
| CO1 | Therapeutic modification of the normal diet |
| CO2 | Nutrition in surgical And Bone & Joint Diseases |
| CO3 | Etiology, manifestations and dietary management-I |
| CO4 | Inborn errors of metabolism, Older children and adolescents |
| CO5 | Etiology, manifestation and dietary management-II |
| CO6 | dietary management in specific Codition |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| **Unit-1: Therapeutic modification of the normal diet** | **7 Hrs** |
|---|---|
| Principles of Diet therapy; Routine Hospital diet; Diet modifications for therapeutic care, enteral and parenteral nutrition | |
| **Unit-2: Nutrition in surgical And Bone & Joint Diseases** | **7 Hrs** |
| Nutrition in surgical conditions -pre and post operative | |

| |
|---|
| Nutrition in bone and joint diseases – Arthritis, osteoarthritis, gout, rheumatoid arthritis |
| **Unit-3: Etiology, manifestations and dietary management -I** **7 Hrs** |
| A) Gastro intestinal tract disorders- Peptic ulcer, diarrhea, constipation<br>B) Mal absorption syndrome – carbohydrates, fat and lactose intolerance, sprue and celiac disease,<br>C) Pregnancy and lactation, Physical changes during pregnancy, Nutritional needs during pregnancy, Lactation D) Geriatric population |
| **Unit-4: Inborn errors of metabolism, Older children and adolescents** **7 Hrs** |
| Introduction, clinical features, dietary management of phenylketonuria, Galactosemia, Alkaptonuria Infants and preschool children, Feeding 0-6 months infant, Feeding 6-12 months infant, Feeding preschoolers, Problems of infants and preschoolers nutrition |
| **Unit-5: Etiology, manifestation and dietary management-II** **7 Hrs** |
| Nutritional management of metabolic disease 1: Diabetes and hypoglycemia, Diet Plan Food exchange list, Glycemic index, CHO counting. Meal planning with and without insulin, Artificial sweeteners and sugar substitutes, Drugs and insulin, Exercise<br>Hypoglycemia- Classification, symptoms, Fasting hypoglycemia, Postprandial or reactive hypoglycemia, early alimentary and late reactive hypoglycemia, Idiopathic hypoglycemia. Dietary treatment in reactive hypoglycemia |
| **Unit-6: dietary management in specific Codition** **5 hours** |
| Etiology, clinical aberrations, prevention and nutritional management of- • Infection • fever (Acute and chronic) • Allergy • Stress • Burns |

**Suggested Reading**:

1. Diet Therapy- Williams
2 Nutrition and Physical fitness: Bogert, L.J.
3 Human Nutrition Mc Durtt, Maxine
4 Applied Nutrition – Rajalakshmi, R.
5 Hand book of diet therapy: Dorothea, Turner.
6 Human Nutrition and dietetics- Davidson, S. Passmore, R. Brock- J.F. and Turswell A.S.
7. Clinical Dietetics and Nutrition - Antia, F.P.
8. Modern Nutrition in health and disease by Goodhearth R., S. Shills

| | | | | |
|---|---|---|---|---|
| Name of The Course | **Nutritional care in disease condition - II** | | | |
| Course Code | **MNAD3002** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives**:

Students will get exposure about the nutritional care in specific disease condition and additional nutritional support system.

**Course Outcomes**

| | |
|---|---|
| CO1 | Nutritional management in infection and fever |
| CO2 | Nutritional support systems |

| | |
|---|---|
| CO3 | Nutritional management of physiological stress |
| CO4 | Nutritional management of GI diseases |
| CO5 | Nutritional Management in diseases of the liver, Pancreas and Biliary system |
| CO6 | Nutritional Management in critical care |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| **Unit-1: Nutritional management in infection and fever 7 Hrs** |
| Defense mechanism, Metabolic changes during infection, Classification and entity of fever infection, Typhoid/ TB / parasitic infestation/ Aids |
| **Unit-2: Nutritional support systems: 7 Hrs** |
| Enteral Nutrition- Site, Size of the tube, Feed-types, Complications<br>Parenteral Nutrition- Type, Composition, Complications<br>Obesity and underweight diet management, Nutritional management of eating disorders |
| **Unit-3: Nutritional management of physiological stress 7 Hrs** |
| Nutrition in wound healing, Surgery: Pre and post surgical dietary management,<br>Burns- Classification, Complication, Dietary management, Trauma: Dietary management, Sepsis: Dietary management |
| **Unit-4: Nutritional management of GI diseases 7 Hrs** |
| Esophagitis(GERD), Dyspepsia, Peptic ulcer, Gastritis, Gastrectomy: Dumping syndrome<br>Flatulence, Diarrhea, Constipation, Hemorrhoids, Diverticular disease, Duodenal ulcer, Inflammatory Diseases of Bowl: Crohn's disease and ulcerative colitis, Irritable bowl syndrome, Colostomy, Ileostomy<br>Malabsorption syndrome- Celiac disease (Tropical sprue), Steatorrhoea, Intestinal Brush border diseases<br>Protein losing enteropathy |
| **Unit-5: Nutritional Management in diseases of the liver, Pancreas and Biliary system 7 Hrs** |
| Progression of liver disease, Metabolic and nutritional Implications, Role of specific nutrients and alcohol in liver diseases. Nutritional care in liver disease in the context of results of specific liver function tests. Viral hepatitis, cirrhosis of Liver, Hepatic encephalopathy, Wilsons disease. Liver transplant<br>Biliary dyskinesia, Cholelithiasis, Cholecystitis, Cholecystectomy, Pancreatitis, Zollinger Ellison syndrome |
| **Unit-6: Nutritional Management in critical care 5 hours** |
| Nutritional screening and nutritional Status assessment of critically ill, Nutritional requirement according to the critical condition |

**Suggested Readings:**

1. Davidson's Human Nutrition – Geissler.
2. Nutrition and Biochemistry for Nurses by Jacob Anthikad
3. Willims S. R.: Essentials of Nutrition and Diet Therapy, 4th ed., Mosby College Pub. S. Louis, 1986. 4. Thomas, B.: Manual of Dietetic Practice, 1996.
4. L. MatareseGottschlich Contemporary Nutrition Support Practice, Saunders 1998
5. ASPEN; Nutrition Support, Dietetics

| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | **Nutritional Management-II** | | | | |
| Course Code | **MNAD3003** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

**Course Objectives:**

Students will get exposure about the nutritional management in different disease condition.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Introduction to Food Service Systems |
| CO2 | Legal Aspects and Personnel Management |
| CO3 | Space Organisation |
| CO4 | Time and Energy Management |
| CO5 | Management of Finance |
| CO6 | Principles of Institutional food Management |

**eContinuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| |
|---|
| **Unit-1: Introduction to Food Service Systems** **7 hours** |
| Evolution of the food service industry, Broad categories of catering services; commercial and Institutional, Characteristics of the various types of food service units, Canteens, Hostels, Hospitals and Restaurants |
| **Unit-2: Legal Aspects and Personnel Management** **7 Hrs** |
| Labour Laws, Welfare policies and schemes for employees, Manpower planning, Recruitment, selection and orientation, Training and motivation |
| **Unit-3: Space Organisation** **7 Hrs** |
| Space requirements for kitchen and service areas, Types of Kitchens, Layout of service areas. Equipment -Types of equipment, Selection of equipment, Maintenance of equipment |
| **Unit-4: Time and Energy Management** **7 Hrs** |
| Importance of time and energy management - Types of energy, Human and fuel energy. Measures for utilization and conservation |
| **Unit-5: Management of Finance** **7 Hrs** |
| Sources of finance, Budgets<br>Food cost analysis, Labour cost analysis, Cost Control Techniques |
| **Unit-6: Principles of Institutional food Management** **5 hours** |
| Management functions, Management tools: Tangible, Intangible tools |

**Suggested Readings:**

1. Food Service in Institutions – Wood

2. Food Service in Institutions – West, Bessin, Brooks.
3. Handbook of Food Preparations – A.M. Home Economics Association.
4. Food Selection and Preparations – Sweetman, M.D.,4, Mackeller.
5. School Lunch Room Service – Oliver B. Watson.
6. Food service Planning: layout Equipment – Lender H. Ketshevar and Marget E. Terrel.
7. Human Nutrition and Dietetics – Davidson and Passmore

| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | **Community Nutrition** | | | | |
| Course Code | **MNAD3004** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

**Course Objectives:**

Students will get exposure about the community nutrition along with hygiene, sanitation and food standards.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Factors affecting food production & conservation |
| CO2 | Nutritional Programmes for improvement of Nutritional status |
| CO3 | Food Service at various organizations |
| CO4 | Food Storage |
| CO5 | Hygiene and Sanitation |
| CO6 | food standards |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content:**

| |
|---|
| **Unit-1: Factors affecting food production & conservation 7 Hrs** |
| Factors affecting food production & conservation- Per capita food availability and consumption, poverty, family planning, social & cultural values, education. II. Nutrition surveillance and planning III. National nutrition Policy. |
| **Unit-2: Nutritional Programmes for improvement of Nutritional status 7 Hrs** |
| Nutrition Education: a Methods b Planning and execution c Evaluation and follow up<br>Menu Planning -Types of menus - Considerations in menu planning - Steps in Menu planning - Planning menus for canteens, cafeterias, boarding school, hostel mess and old age homes |
| **Unit-3: Food Service 7 Hrs** |

| |
|---|
| Styles of food service in restaurants -Food service in hospitals -Food service in institutions Food management -Purchasing: principles, purchasing process and methods -Receiving: receiving process delivery methods and procedure - Issuing process, |
| **Unit-4: Food Storage** **7 Hrs** |
| Layout of stores, Storage procedure, Inventory management, Store Records<br>Food Production Management -Food production process,Large quantity cooking techniques, Holding food |
| **Unit-5: Hygiene and Sanitation** **7 Hrs** |
| Bractical agents: Salmonella, Staphylococcus, Clostridium,, E. coli, Vibrio Fungal agents: Aspergillus, Fusarium, penicillium. Viruses Polio, Hepatitis. Protozoa: Giardia, Entamoeba Morphology, cultural and biochemical characteristics of Salmonella, Staphylococus, Clostridiun, E. coli, Vibrio cholerae, Streptococus lactis, Lactobacillus, Saccharmyces cerevisiae. Microbiological criteria for food testing and Quality control. |
| **Unit-6: Food Standards** **5 hours** |
| The HACCP system and food safety used in controlling microbiological hazards. Food sanitation – Microbiology of food plant sanitation, water and milk testing |

**Suggested Readings:**

1. Food Service in Institutions – Wood
2 Food Service in Institutions – West, Bessin, Brooks.
3 Handbook of Food Preparations – A.M. Home Economics Association.
4 Food Selection and Preparations – Sweetman, M.D., 4, Mackeller.
5 School Lunch Room Service – Oliver B. Watson.
6. Food service Planning: layout Equipment – Lender H. Ketshevar and Marget E. Terrel.
7. Human Nutrition and Dietetics – Davidson and Passmore

| Name of The Course | **Nutraceuticals and Functional foods- II** | | | |
|---|---|---|---|---|
| Course Code | **MNAD3005** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

**Course Objectives:**

Students will get exposure about the neutraceutical and functional food in different disease condition.

**Course Outcomes**

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Applications of herbs to functional foods |
| CO2 | Source and role of functional foods |
| CO3 | Nutritional genomics |
| CO4 | production of proteins for pharmaceutical and industrial uses. |
| CO5 | New technologies in development of Nutraceuticals & functional foods |
| CO6 | Application of bioprocess technology in nutraceuticals |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

**Course Content**

| | |
|---|---|
| **Unit-1: Functional Foods- I** | **7 hours** |
| Definition, Relation of functional foods & Nutraceutical (FFN) to foods & drugs. Applications of herbs to functional foods. Concept of free radicals and antioxidants; Nutritive and Non-nutritive food components with potential health effects. Effect of processing on Nutrients. Soy proteins and soy isoflavones in human health; Role of nuts in cardiovascular disease prevention. Functional foods from wheat and rice and their health effects. Role of Dietary fibers in disease prevention. | |
| **Unit-2: Functional Foods-II** | **7 hours** |
| Sources and role of Isoprenoids, Isoflavones, Flavonoids, carotenoids, Tocotrienols, polyunsaturated fatty acids, sphingolipids, lecithin, choline. terpenoids. Vegetables, Cereals, milk and dairy products as Functional foods. Health effects of common beans, Capsicum annum, mustards, Ginseng, garlic, grape, citrus fruits, fish oils, and sea foods | |
| **Unit-3: Nutritional Genomics-I** | **7 hours** |
| Production technology for recombinant therapeutic products using E.coli with examples like human insulin, growth hormones, interferons, erythropoietin | |
| **Unit-4 : Nutritional Genomics – II** | **7 hours** |
| Plants as bioreactors as a tool for production of Nutraceuticals. 'Tailor-made' carbohydrates and lipids of plant and non-plant origin. Transgenic plants for the large scale production of proteins for pharmaceutical and industrial uses. Plants as an alternative for biotransformation of raw materials into special chemicals. | |
| **Unit-5: New technologies in development of Nutraceuticals & functional foods** | **7 hours** |
| Supercritical food extraction technology-basics and application for extraction of nutraceuticals from various sources, Application of pressurized low polarity water extraction, use of membranes separation technology, distillation and dehydration technologies | |
| **Unit- 6: Application of bioprocess technology in nutraceuticals** | **5 hours** |
| Application of bioprocess technology for production and enhancement of properties of nutraceuticals | |

**Suggested Readings:**

1) Nutraceuticals: Efficacy, Safety and Toxicity by Ramesh C. Gupta

2) Nutraceuticals: The Complete Encyclopedia of Supplements, Herbs, Vitamins and Healing Foods by Arthur J. Roberts, Genelle Subak-Sharpe, et al.

3) Advances in Nutraceutical Applications in Cancer: Recent Research Trends and Clinical Applications (Nutraceuticals) by Sheeba Varghese Gupta and Yashwant V Pathak

4) Nutraceuticals in Health and Disease Prevention (Infectious Disease and Therapy Book 6) by PETER. PAUL HOPPE, Klaus Kramer, et al.

5) Nutrigenomics and Nutraceuticals: Clinical Relevance and Disease Prevention by Yashwant V. Pathak and Ali M. Ardekani

6) Pharmaceuticals to Nutraceuticals: A Shift in Disease Prevention by Dilip Ghosh and R. B. Smarta

7) Handbook of Nutraceuticals and Functional Foods (Modern Nutrition) by Robert E.C. Wildman and Richard S. Bruno

# Semester-IV

| Name of The Course | **Project and dissertation** | | | |
|---|---|---|---|---|
| Course Code | **MNAD4001** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 0 | 0 | 26 | 13 |

**Course Objectives:**
Students will get exposure of Project work execution in the area of Nutrition and Dietetics.

**Course Outcomes:**
On completion of this course the students will be able to

| | |
|---|---|
| CO1 | Formulate questions and to discover feasible solutions |
| CO2 | Demonstrate individual initiative or group responsibility |
| CO3 | Use resource materials to express ideas and talents |
| CO4 | Design and execute the project work |
| CO5 | Report the project work in terms of thesis |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **60** | **00** | **240** | **300** |

## Course Content

| **Unit-1: Project and dissertation** | **9 hours** |
|---|---|
| This project work is to make the student acquainted with the Patient/Healthcare sector/ industrial/ Sports person. After completion of the project they will have to submit dissertation report<br>This project work or thesis presents a student's research results, describing the research with reference to relevant work done as part of the live project at a Hospital/Healthcare sector/Patients with specific diseases and sports person.<br>It will include a description of the methods of research considered, and those actually employed, and present the student's conclusions. The thesis is the student's own work and must be written by the student.<br><br>The Internal Layout of the project work or Thesis<br>The thesis is to be submitted in the following pattern,<br><br>□ Title page;<br>□ Summary (Abstract)<br>□ Table of contents | |

- ☐ List of tables
- ☐ List of figures
- ☐ Definitions or Abbreviations;
- ☐ Declarations and Statements
- ☐ Acknowledgement
- ☐ Author's declaration
- ☐ Contents page;
- ☐ Introduction
- ☐ Study Objectives
- ☐ Subject selection and withdrawal
- ☐ Study nutrition/management
- ☐ Statistical Plan
- ☐ Safety and adverse event's
- ☐ Glossary
- ☐ List of references
- ☐ Bibliography
- ☐ Index

GALGOTIAS UNIVERSITY

(Established under Galgotias University Uttar Pradesh Act No. 14 of 2011)

# Program: B. Tech. Biomedical Engineering

**Scheme: 2020-2021**

**Vision: To be known globally for education, innovation and interdisciplinary research in Biosciences, Healthcare and Biomedical Engineering**

## Mission

**M1**. To establish the centre of excellence in biomedical sciences & engineering.

**M2**. To establish state-of-the-art facilities of Biomedical Sciences & Engineering for world class education and research.

**M3**. To conduct the multidisciplinary research in collaboration with national and international organization for developing the innovative solutions of unsolved health problems.

**M4**. To develop Bio-engineering leaders having regulatory and ethical mind set with capability of creating value in biomedical industry.

## Program Educational Objectives (PEO)

**PEO 1**. Graduates shall conduct the research in healthcare, biomedical science and interdisciplinary field efficiently and ethically.

**PEO 2**. Graduates of biomedical engineering shall excel in higher studies and interdisciplinary research exhibiting global competitiveness.

**PEO 3.** Graduates have a high sense of medical responsibilities and ethical thinking and solve new/ unsolved/ unmet biomedical need.

## Program Specific Outcomes (PSO)

Graduates of Biomedical Engineering shall be able to

**PSO1.** Evaluate critical domestic and global regulatory and health care issues that challenge and influence biomedical product development

**PSO2**. Demonstrate competencies in performing the biomedical research; evaluating, analysing and presenting the biomedical research results.

**PSO3**. Effectively communicate and collaborate with health care providers and regulatory agencies to develop culturally diverse domestic and global strategies for medical device approvals

**PSO4**. Demonstrate regulations, social and ethical values required to make a global biomedical research professional.

## Program Outcomes

**PO1- Biomedical Engineering Knowledge**: Possess knowledge and comprehension of the core and basic knowledge associated with the profession of Biomedical Engineering, including Medical Instrumentation, Biomedical Circuits and Networks, Biomedical Control Systems, Biomaterials and Artificial Organs, Medical signal/image processing and analysis and Virtual Instrumentation Design For Medical Systems.

**PO2- Planning Abilities**: Demonstrate effective planning abilities including waste management, hospital management, Disaster management, delegation skills and organizational skills. Develop and implement plans and organize work to meet deadlines.

**PO3- Problem analysis**: Utilize the principles of Analytical thinking, clearly and critically, while solving problems and making decisions during development of medical devices. Find, analyse, evaluate and apply information systematically and making decisions related to biomedical research.

**PO4- Modern tool usage**: Learn and apply modern and appropriate tools related to biomedical research.

**PO5- Leadership skills**: Understand and consider the human reaction to change, motivation issues, leadership and team-building when planning changes required for fulfilment of practice, professional and societal responsibilities. Assume participatory roles as responsible citizens or leadership roles during the conduction of biomedical research to facilitate improvement in health and wellbeing.

**PO6- Professional Identity**: Understand, analyse and communicate the value of their professional roles in society

**PO7- Biomedical Engineering Ethics:** Honour human values and apply ethical principles in professional and social contexts. Demonstrate behaviour that recognizes cultural and personal variability in values, communication and lifestyles. Use ethical frameworks; apply ethical principles while making decisions during the conduction of biomedical research.

**PO8- Communication:** Communicate effectively with the biomedical research & healthcare community.

**PO9- Biomedical Engineering and society**: Apply reasoning informed by the contextual knowledge to assess societal, health, safety and legal issues and the consequent responsibilities relevant to the biomedical research practice.

**PO10- Environment and sustainability**: Understand the impact of the biomedical research solution in societal and environmental contexts, demonstrate the knowledge of, and need for sustainable development.

**PO11- Life-long learning:** Recognize the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change. Self-access and use feedback effectively from others to identify learning needs and to satisfy these needs on an ongoing basis.

## Curriculum

### Semester III

| Sl. No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BMET 3001 | Human Physiology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMET 3002 | Medical Instrumentation-I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BMET 3003 | Analog and digital electronics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BMET 3004 | Engineering mathematics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | BMET 3005 | Biomedical Circuits and Networks | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | SLLL | Ethics and Professional Competency | 1 | 0 | 0 | 1 | 20 | 30 | 50 |
| 7 | BMET 3007/8 | Elective-I | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 8 | BMEP 3051 | Physiology Lab | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| 9 | BMEP 3052 | Bio-electronics Lab | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| 10 | BMEP 3053 | Medical Instrumentation-I Lab | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| 11 | SOLE | Aptitude building and Logical Reasoning | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| | | **Total** | | | | | | | |

### Semester IV

| Sl No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BMET 4001 | Biomedical Control Systems | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMET 4002 | Medical Instrumentation-II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BMET 4003 | Biomaterials and Artificial Organs | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BMET 4004 | Medical Informatics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | BMET 4005 | Data structure using C | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | BMET 4006/7 | Elective-II | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 7 | BMEP 4051 | Biomedical Control Systems Lab | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| 8 | SOLE | Aptitude building and Logical Reasoning | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| 9 | BMEP 4052 | Medical Instrumentation-II Lab | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| **10** | BMEP 4053 | Data structure using C | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| | | **Total** | | | | | | | |

### Semester V

| Sl No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BMET 5001 | Research Methodology and Biostatistics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMET 5002 | Medical signal & Image processing | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BMET 5003 | Tissue Engineering & Microfluidics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BMET 5004 | Bioethics and Biosafety | 3 | 0 | 0 | 3 | 20 | 30 | 50 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 5 | BMET 5005 | Biopotentials | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | BMET 5006/7 | Elective-III | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| **7** | BMEP 5051 | Medical signal & Image processing Lab | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| **8** | BMEP 5052 | Molecular Biology and Genetics Lab | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| **9** | BMEP 5053 | Biopotentials Lab | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| **10** | SOLE | Aptitude building and Logical Reasoning | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| | | **Total** | | | | | | | |

**Semester VI**

| **Sl No** | **Course Code** | **Name of the Course** | | | | | **Assessment Pattern** | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| 1 | BMET 6001 | Biophysics & Biochemistry | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMET 6002 | Automation And Quality Control In Biomedical Engineering | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BMET 6004 | Virtual Instrumentation Design For Medical Systems | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BMET 6005 | Advanced Biomedical Instrumentation | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | BMET 6006/7 | Elective-IV | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | BMEP 6051 | Biophysics & Biochemistry Lab | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| **7** | BMEP 6052 | Automation And Quality Control In Biomedical Engineering Lab | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| **8** | BMEP 6054 | Virtual Instrumentation Design and AI Lab | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| **9** | SOLE | Aptitude building and Logical Reasoning | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| **10** | BMEP 6055 | Campus to corporate/UG Project/ Industrial Training | 0 | 0 | 6 | 3 | 50 | -- | 50 |
| | | **Total** | | | | | | | |

**Semester VII**

| **Sl No** | **Course Code** | **Name of the Course** | | | | | **Assessment Pattern** | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **L** | **T** | **P** | **C** | **IA** | **MTE** | **ETE** |
| 1 | BMET 7001 | BioMEMS and Biosensors | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMET 7002 | Artificial Intelligence & Pattern Recognition | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 3 | BMET 7003 | Modeling of Physiological System | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 4 | BMET 7004 | Hospital and Healthcare Administration | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 5 | BMET 7005 | Fundamentals of Clinical Research | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 6 | BMET 7006/7 | Elective-V | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| **7** | SLLL | Disaster Management | 2 | 0 | 0 | 2 | 20 | 30 | 50 |
| **8** | BMEP 7051 | Artificial Intelligence & Pattern Recognition Lab | 0 | 0 | 2 | 1 | 50 | -- | 50 |
| **9** | BLE601/ BLE602/BLE603 | Foreign Language - 1 (German, Japneese, French) *Compulsory Open Elective | 0 | 0 | 4 | 2 | 50 | -- | 50 |
| | | **Total** | | | | | | | |

# School of Biosciences and Biomedical Engineering

| Semester VIII | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sl No | Course Code | Name of the Course | | | | | Assessment Pattern | | |
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BMEP 8051 | Major Project | 0 | 0 | 24 | 12 | 60 | -- | 240 |

## List of Electives

**Elective-I**

| Sl No | Course Code | Name of the Electives | | | | | Assessment Pattern | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BMET 3007 | Electronic Measurement and Instrumentation for Biomedical Applications | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMET 3008 | Introduction to Biotechnology | 3 | 0 | 0 | 3 | 20 | 30 | 50 |

**Elective-II**

| Sl No | Course Code | Name of the Electives | | | | | Assessment Pattern | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BMET 4006 | Biomechanics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMET 4007 | Microprocessors and MicroControllers | 3 | 0 | 0 | 3 | 20 | 30 | 50 |

**Elective-III**

| Sl No | Course Code | Name of the Electives | | | | | Assessment Pattern | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BMET 5006 | Linear Integrated Circuits | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMET 5007 | Drug Discovery and Development | 3 | 0 | 0 | 3 | 20 | 30 | 50 |

**Elective-IV**

| Sl No | Course Code | Name of the Electives | | | | | Assessment Pattern | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BMET 6006 | VLSI Design | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMET 6007 | Biotransport Process | 3 | 0 | 0 | 3 | 20 | 30 | 50 |

**Elective-V**

| Sl No | Course Code | Name of the Electives | | | | | Assessment Pattern | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | L | T | P | C | IA | MTE | ETE |
| 1 | BMET 7006 | Introduction to Bioinformatics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |
| 2 | BMET 7007 | Molecular Diagnostics & Therapeutics | 3 | 0 | 0 | 3 | 20 | 30 | 50 |

# Semester III

| Name of The Course | Human Physiology | | | |
|---|---|---|---|---|
| Course Code | BMET 3001 | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives:
Students will understand about the structure and functions of the organ-systems of our own body.

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Circulatory and Lymphatic System |
| CO2 | Understand the Endocrine system & Sensory system |
| CO3 | Understand the Respiratory system |
| CO4 | Understand the Musculo-skeletal System & Urinary system |
| CO5 | Understand about the Nervous system |
| CO6 | Analyse the Digestive system |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Circulatory and Lymphatic System | 7 hours |
| Anatomy of the heart and the blood vessels. Heartposition and function. Origin of the heart beat and electrical activity of the heart. Arteries, capillaries and veins- structure and function. Cardiac and peripheral circulation. Blood pressure and its regulation. Blood flow and its regulation. Circulatory shock. Lymph and dynamics of lymph flow. Blood composition and function. Structure and function of red blood cells, white blood cells and platelets. Blood transfusion. Hemostasis. | |
| Unit-2: Endocrine system & Sensory system | 7 hours |
| Endocrinology: Endocrine glands: Pituitary gland and hormone, thyroid gland and its hormone, adrenal gland and its hormone function, basic mechanism of hormone action, hormones and diseases. Sensory system: Functional anatomy of eye, ear and nose. Skin | |
| Unit-3: Respiratory system | 7 hours |
| Anatomical parts of the system and function. Mechanics of respiration. Lung volumes and capacities. Gas transport between the lungs and tissues. Regulation of respiration. Respiratory adjustments in health and diseases; | |
| Unit-4: Musculo-skeletal System & Urinary system | 7 hours |
| Different types of muscles and their characteristics. Neuro-muscular transmission. Structure of bone. General description of joints and structure. Disorders of: neuromuscular apparatus and joints; Various parts, structure and functions of the kidney and urinary tract. Physiology of urine formation and acid base balance. Diseases of the urinary system with reference to drugs used | |
| Unit-5: Nervous system | 7 hours |
| Functions of different parts of brain and spinal card. Neurohumoral transmission in the central nervous system, reflex action, electroencephalogram, specialized functions of the brain, cranial nerves and their functions; Physiology and functions of the autonomic nervous system. Mechanism of Neurohumoral transmission in ANS | |

| Unit-6: Digestive system hours | 5 |
|---|---|
| Different parts of the digestive system. Structure and function of these organs. Digestion of proteins, carbohydrates, fats. Basic mechanism of gastrointestinal absorption of nutrients. | |

Suggested Readings:


1. Text Book of Medical Physiology, Guyton & Hall, W.B. Saunders company. Hardcourt India Private Limited
2. Ganongs Review of Medical Physiology. K E Barrett, S M Barman, S Boitano, H L Brooks, Tata McGraw Hill Education Private Limited.
3. Vander's Human Physiology: The Mechanisms of Body Function. Eric P. Widmaier, Hershel Raff, Kevin T. Strang. McGraw Hill
4. Ross and Wilson Anatomy and Physiology in Health and Illness by Anne Waugh, Elsevier


| Name of The Course | Medical Instrumentation-I | | | |
|---|---|---|---|---|
| Course Code | BMET 3002 | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives:
Students will understand about the Medical Instrumentations

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Bio Potential Electrodes |
| CO2 | Understand the Electrode Configurations |
| CO3 | Understand the Bio Amplifier |
| CO4 | Understand the Measurement of Non-Electrical Parameter |
| CO5 | Understand about the Bio-Chemical Measurement |
| CO6 | Analyze the Cardiac pacemakers & defibrillators |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| Unit-1: Bio Potential Electrodes | 7 hours |
|---|---|
| Origin of bio potential and its propagation. Electrode-electrolyte interface, electrode–Skin interface, half cell potential, impedance, polarization effects of electrode –nonpolarizable electrodes. Types of electrodes - surface, needle and micro electrodes and their equivalent circuits. Recording problems - measurement with two electrodes. | |
| Unit-2: Electrode Configurations | 7 hours |

| | |
|---|---|
| Biosignals characteristics – frequency and amplitude ranges. ECG – Einthoven's triangle, standard 12 lead system. EEG – 10-20 electrode system, unipolar, bipolar and average mode. EMG, ERG and EOG – unipolar and bipolar mode. | |
| Unit-3: Bio Amplifier | 7 hours |
| Need for bio-amplifier - single ended bio-amplifier, differential bio-amplifier – right leg driven ECG amplifier. Band pass filtering, isolation amplifiers – transformer and optical isolation - isolated DC amplifier and AC carrier amplifier. Chopper amplifier. Power line interference. | |
| Unit-4: Measurement of Non-Electrical Parameter | 7 hours |
| Temperature, respiration rate and pulse rate measurements. Blood Pressure: indirect methods - auscultatory method, oscillometric method, direct methods: electronic manometer, Pressure amplifiers - systolic, diastolic, mean detector circuit. Blood flow and cardiac output measurement: Indicator dilution, thermal dilution and dye dilution method, Electromagnetic and ultrasound blood flow measurement. | |
| Unit-5: Bio-Chemical Measurement | 7 hours |
| Biochemical sensors - pH, pO2 and pCo2, Ion selective Field effect Transistor (ISFET), Immunologically sensitive FET (IMFET), Blood glucose sensors - Blood gas analyzers, colorimeter, flame photometer, spectrophotometer, blood cell counter, auto analyser (simplified schematic description). | |
| Unit-6: Cardiac pacemakers & defibrillators | 5 hours |
| Cardiac pacemakers:Classification –External and internal (implantable) pacemakers,Synchronous and asynchronouspacemakers, programmable pacemakers, power sources, Pacing system analyzers. Cardiac defibrillators:Classification–AC and DC defibrillators, Biphasic and Monophasic, Basic principles and comparison of output waveforms of different DC defibrillators, Energy requirements,Synchronous, manual and asynchronous operation, implantable defibrillators, defibrillatoranalyzers, AED. | |

Suggested Readings:

1. John G. Webster, "Medical Instrumentation Application and Design", John Wiley and sons, New York, 2004
2. Joseph J. Carr and John M. Brown, "Introduction to Biomedical Equipment Technology", Pearson Education, 2004.
3. Leslie Cromwell, "Biomedical Instrumentation and measurement", Prentice hall of India, New Delhi, 2007.
4. Khandpur R.S, "Handbook of Biomedical Instrumentation", Tata McGraw-Hill, New Delhi, 2003.
5. Standard Handbook of Biomedical Engineering & Design – Myer Kutz, McGrawHill Publisher, 2003.

| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | Analog and digital electronics | | | | |
| Course Code | BMET 3003 | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

Course Objectives:
Students will understand about the Analog and digital electronics

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Large Signal Amplifiers |
| CO2 | Understand the Multistage Amplifiers |
| CO3 | Understand the Introduction to IC |
| CO4 | Understand the Sequential Circuits |
| CO5 | Understand about the D/A and A/D Converters |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Couse Contents

| | |
|---|---|
| Unit-1: Large Signal Amplifiers | 7 hours |
| Class A direct coupled with resistive load, Transformer coupled with resistive load, design theory, power amplifier design, harmonic distortion, power output, variation of output power with load, thermal runaway, output transformer saturation, push-pull amplifiers, operation of class-A push-pull amplifier, class-B push-pull amplifier, crossover distortion, class AB push-pull amplifier, transistor phase inverter, conversion efficiency of class B amplifiers, design of Class-B push-pull amplifier, complementary symmetry amplifier. | |
| Unit-2: Multistage Amplifiers | 7 hours |
| Coupling of transistor amplifiers, frequency response of coupled amplifiers, cascading of RC coupled amplifiers and their analysis. Tuned Amplifiers: single tuned, double tuned and stagger tuned amplifiers and their analysis. Types of feedback, effect of negative feedback on gain, bandwidth, stability, distortion and frequency response etc. Voltage series, current series, voltage shunt, current shunt feedback circuits and their analysis | |
| Unit-3: Introduction to IC | 7 hours |
| Advantages of IC's, General classification of IC's (Linear/Digital IC's, Monolithic/ Hybrid IC's), Basic IC fabrication step | |
| Unit-4: Sequential Circuits | 7 hours |
| Introduction, flip flop SR, JK, D, T edge triggered and decked flip-flop, Registers. Type of Registers, circuit diagram, timing wave form and operation counters, counter design with state equation and state diagrams | |
| Unit-5: D/A Converters | 7 hours |
| Introduction, Weighted register D/A converter, binary ladder D/A converter, steady state accuracy test, D/A accuracy and resolution, Voltage of frequency conversion, Voltage of time conversion. Analog multiplexes and demultiplexes | |
| Unit-6: A/D Converters | 5 hours |
| Parallel A/D converter, Counter type A/D converter Successive approximation A/D converter. Single and dual slope A/D converter A/D accuracy and resolution | |

Suggested Readings:

1. Millman and Halkias : Electronic Devices & Circuits, TMH.
2. Boylestad : Electronic Devices & Circuits Theory, PH.
3. Allen Mottorshead : Electronic Devices & Circuits, PHI.
4. Malvino : Digital principle and applications, TMH.
5. R.P.Jain : Modern digital electronics, PIH.
6. Malvino : Digital electronics principle, THM

| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | Engineering mathematics | | | | |
| Course Code | BMET 3004 | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

Course Objectives:
Students will understand about the coordinate geometry, derivatives, integration, differentiation and differential calculus.

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the concept of Coordinate Geometry |
| CO2 | Understand the concept of derivatives on rate of change, functions and variables |
| CO3 | Understand the concept of integration on Curves, Volumes and length |
| CO4 | Understand the concept of differentiation and apply for finding the solution of differential equations. |
| CO5 | Understand about the differential calculus on Kinematics, rate of change, and optimization. |
| CO6 | Analyze the concept of Differentiation rule |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course contents

| | |
|---|---|
| Unit-1: Coordinate Geometry | 7 hours |
| Conic Sections: Sections of a cone: circle, ellipse, parabola, hyperbola and pair of intersecting lines. Standard equations and simple properties of parabola, ellipse and hyperbola. Standard equation of a circle, with numerical examples | |
| Unit-2: Applications of Derivatives | 7 hours |
| Applications of derivatives: rate of change, increasing/decreasing functions, tangents &normals, approximation and errors, maxima and minima of one variable. Simple problems (that illustrate basic principles and understanding of the subject as well as real-life situations). | |
| Unit-3: Application of integration | 7 hours |
| Areas Between Curves, Volumes, Volumes by Cylindrical Shells, Arc Length | |
| Unit-4: Differential equation | 7 hours |
| Definition, order and degree, general and particular solutions of a differential equation. Formation of differential equation whose general solution is given. Solution of differential equations by method of separation of variables, homogeneous differential equations of first order, and first degree. Solutions of linear differential equation of the type: , where p and q are functions of x. q py dx dy | |
| Unit-5: application of differential calculus | 7 hours |
| Kinematics, rate of change, optimization. | |
| Unit-6: Differentiation rule | 5 hours |
| The Limit of a Function, Calculating Limits Using the Limit Laws, The Precise Definition of a Limit, Continuity, Derivatives of Polynomials and Exponential Functions, The Product and Quotient Rules, Derivatives of Trigonometric Functions, Chain rule, Differentiation of implicit & explicit function , Derivatives of Logarithmic Functions. Roll's and Lagrange's mean value theorem. | |

Suggested Readings:

1) Oldham K, Spanier J. The fractional calculus theory and applications of differentiation and integration to arbitrary order. Elsevier; 1974 Sep 5.
2) Eisenhart LP. Coordinate geometry. Courier Corporation; 2005 Mar 4.
3) Grewal BS. Higher engineering mathematics. 2002, Khanna Publishers, New Delhi. 1996.

| Name of The Course | Biomedical Circuits and Networks | | | |
|---|---|---|---|---|
| Course Code | BMET 3005 | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives:
Students will understand about the Biomedical Circuits and Networks

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Resonant & Coupled Circuits |
| CO2 | Understand the Mesh Current & Node Voltage Network Analysis |
| CO3 | Understand the Network Theorems |
| CO4 | Understand the Circuit Transients |
| CO5 | Understand about the Laplace Transform |
| CO6 | Analyse the Graph of Network |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents:

| | |
|---|---|
| Unit-1: Resonant & Coupled Circuits | 7 hours |
| Resonant Circuits: Series and Parallel Resonance, Impedance and Admittance Characteristics, Quality Factor, Half-Power Points, Bandwidth, Resonant voltage rise, Transform diagrams, Solution of Problems; Coupled Circuits: Magnetic Coupling, polarity of coils, polarity of induced voltage, concept of self and mutual inductance, coefficient of coupling, Solution of Problems | |
| Unit-2: Mesh Current & Node Voltage Network Analysis | 7 hours |
| Mesh Current Network Analysis: Kirchoff's Voltage Law, Formulation of Mesh Equations, Solution of mesh equations by Cramer's rule and matrix method, Driving point impedance, Transfer impedance, Solutions of Problems with DC and AC sources; Node Voltage Network Analysis: Kirchoff's Current Law, Formulation of node equations and solutions, Driving point admittance, Transfer admittance, Solutions of Problems with DC and AC sources | |
| Unit-3: Network Theorems | 7 hours |
| Network Theorems: Definition and implications of Superposition Theorem, Thevenin's Theorem, Norton's Theorem, Reciprocity Theorem, Compensation Theorem, Maximum Power Transfer Theorem, Millman's Theorem, Star-Delta transformations, Solutions and Problems with DC and AC sources; SPICE: Introduction, model statement, elementary DC and small-signal analysis | |
| Unit-4: Circuit Transients | 7 hours |
| Circuit Transients: DC Transient in R-L & R-C circuits with and without initial charge, R-L-C circuits, AC transients in sinusoidal R-L, R-C, & R-L-C circuits, solution of problems | |
| Unit-5: Laplace Transform | 7 hours |

| |
|---|
| Laplace Transform: Concept of complex frequency, transformation of f(t) into F(s), transformation of step, exponential, overdamped surge, critically damped surge, damped sine, undamped sine functions, properties of Laplace Transform, linearity, real-differentiation, realintegration, Initial Value Theorem and Final Value Theorem, Inverse Laplace Transform, applications in circuit analysis, Partial Fractions expansion, Heaviside's Expansion Theorem, solution of problems |
| Unit-6: Graph of Network 5 hours |
| Graph of Network: Concept of Tree Branch, Tree link, junctions, Incident matrix, Tie-set matrix, Cut-set matrix, determination of loop current and node voltages. |

Suggested Readings:

1. A.B.Carlson-Circuits- Cenage Learning
2. John Bird- Electrical Circuit Theory and Technology- 3/e- Elsevier (Indian Reprint)
3. Skilling H.H.: "Electrical Engineering Circuits", John Wiley & Sons.
4. Edminister J.A.: "Theory & Problems of Electric Circuits", McGraw-Hill Co.
5. Kuo F. F., "Network Analysis & Synthesis", John Wiley & Sons.
6. R.A.DeCarlo & P.M.Lin- Linear Circuit Analysis- Oxford 7. P.Ramesh Babu- Electrical Circuit Analysis- Scitech

# Elective-I

| Name of The Course | Electronic Measurement and Instrumentation for Biomedical Applications | | | |
|---|---|---|---|---|
| Course Code | BMET 3007 | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives:

Students will understand about the basics of sensors and transducers, by which the students can able to know the use and the type of sensors/transducer with other signal conditioning circuit for various biomedical applications.

Course Outcomes:

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Basic concept of measurement system |
| CO2 | Explain the Introduction to instrumentation system |
| CO3 | Understand the Principles of transduction |
| CO4 | Understand the Signal Conditional Circuit |
| CO5 | Understand the Indicating and recording instruments |
| CO6 | Analyse the Introduction of Power electronics devices: |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents:

| | |
|---|---|
| Unit-1: Basic concept of measurement system | 7 hours |

| |
|---|
| Basic concept of measurement system, role of noise and errors in measurement, static characteristics of measuring devices - accuracy, precision, sensitivity, resolution, hysterisis, loading effect etc. |
| Unit-2: Introduction to instrumentation system 5 hours |
| Introduction to instrumentation system, performance characteristics of instrumentation system – system order, specification and testing of dynamic response. Concept of control system, classification, block diagram representation of physical system. |
| Unit-3: Principles of transduction 7 hours |
| Principles of transduction, Resistive Transducers Strain Gauge- types, construction, selection materials, Gauge factor, Bridge circuit, Temperature compensation. Strain Gauge type Blood pressure transducers. Thermo resistive transducer, Pressure transducers – diaphragms, thin film, piezoelectric, force balanced pressure meter. Flow transducers. |
| Unit-4: Signal Conditional Circuit 7 hours |
| Types of filters, frequency transformation, realization of practical filters and its biomedical application. |
| Unit-5: Indicating and recording instruments 7 hours |
| Introduction, digital voltmeters (DVM's), galvanometric recorders, servo type potentiometric recorders, thermal, inkjet, laser recorders, magnetic tape recorders, digital recorder of memory type. |
| Unit-6: Introduction of Power electronics devices: 7 hours |
| Thyristor characteristic and its application as rectifier, as inverter, chopper and cyclo-converters. Other power transistor and IBGT. |

Suggested Readings:


1. Doebelin, Ernest. *System dynamics: modeling, analysis, simulation, design*. CRC Press, 1998
2. Nakra, B. C., and K. K. Chaudhry. *Instrumentation, measurement and analysis*. Tata McGraw-Hill Education, 2003
3. Helfrick, Albert D., and William David Cooper. *Modern electronic instrumentation and measurement techniques*. Prentice Hall, 1990
4. Kalsi, H. S. *Electronic Instrumentation, 3e*. Tata McGraw-Hill Education, 2010


| | | | | |
|---|---|---|---|---|
| Name of The Course | Introduction to Biotechnology | | | |
| Course Code | BMET 3008 | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| L | T | P | C | |
| 3 | 0 | 0 | 3 | |

Course Objectives:

The students will be familiarized with Genetics, Molecular Biology, Biotechnology and Immunology.

Course Outcomes

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Genetic of Inheritance, interaction between traits and quantitative inheritance |
| CO2 | Molecular Biology, transcription, translation. Mutation and mutagenesis |
| CO3 | Genetic Engineering, vectors & enzymes used in recombinant technology |
| CO4 | Understanding the immunology and vaccine production |
| CO5 | Analyze the red and white biotechnology application |
| CO6 | Analyze the yellow and green biotechnology application |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Content:

| |
|---|
| Unit-1: Genetics 7 hours |
| Genetics of Inheritance - Laws of inheritance, recombination and segregation of traits, segregation ratio, interaction between traits and quantitative inheritance |
| Unit-2: Molecular Biology 7 hours |
| Molecular Biology - The genetic material. RNA as genetic material, fidelity of DNA replication, transcription, translation. Mutation and mutagenesis. |
| Unit-3: Genetic Engineering 7 hours |
| Genetic Engineering - Essentials of gene manipulation, vectors & enzymes used in recombinant technology. |
| Unit-4 : Immunology 7 hours |
| Active, passive, Humoral and Cellular immunity; Clonal selection theory, Cells of immune system; Immunoglobulins, Haptens, Antigens and Immunogens; Monoclonal antibodies; vaccine |
| Unit-5: Application of Biotechnology-I 7 hours |
| Red biotechnology (Medicine & human health); White biotechnology (Industrial process involving microorganisms) |
| Unit-6: Application of Biotechnology-II 5 hours |
| Yellow biotechnology (Insect Biotechnology in Drug Discovery and Preclinical Research); Green biotechnology (Genetically modified crops) |

Suggested Readings:


6. Elements of Genetics; Phundan singh
7. Genetics: B D Singh
8. A textbook of molecular biology: 3rd edition: Mohan p arora and Himanshu Arora
9. Basic Biotechnology: B D Singh
10. Basic and Clinical Immunology: Mark Peakman and Diego Vergani


# Semester IV

| Name of The Course | Biomedical Control Systems | | | | |
|---|---|---|---|---|---|
| Course Code | BMET 4001 | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

Course Objectives:
Students will understand about the Biomedical Control Systems

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Introduction to Physiological control systems |
| CO2 | Understand the Cardiovascular system Modelling and simulation |
| CO3 | Understand the Pulmonary mechanics modeling and simulation |

| | |
|---|---|
| CO4 | Understand the Eye movement system and its mathematical model |
| CO5 | Understand about the Simple models of muscle stretch reflex action |
| CO6 | Analyze the Applications of Control theory to physiological systems |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Introduction to Physiological control systems | 7 hours |
| Introduction to Physiological control systems, Illustration, Example of a physiological control system, Difference between engineering and physiological control system, Art of modeling Physiological systems, Linear models of physiological systems, Distributed parameters versus lumped parameter models, Principle of superposition. | |
| Unit-2: Cardiovascular system Modelling and simulation | 7 hours |
| Cardiovascular system_ Modelling and simulation, Theoretical basis, Model development, Heart model, circulatory model | |
| Unit-3: Pulmonary mechanics modeling and simulation | 7 hours |
| Pulmonary mechanics modeling and simulation, Theoretical basis, Model development, Lung tissue visco-elastance, chest wall, airways, Full model of respiratory mechanics, Interaction of Pulmonary and Cardiovascular models; Study of frequency domain analysis of linearized model of lungs mechanics, | |
| Unit-4: Eye movement system and its mathematical model | 7 hours |
| Eye movement system and its mathematical model, oculomotor muscle model, linear muscle model. | |
| Unit-5: Simple models of muscle stretch reflex action | 7 hours |
| Simple models of muscle stretch reflex action, Ventilator control action, Lung mechanics and their SIMULINK implementation, Study of steady state analysis of muscle stretch reflex action, ventilatory control action by MATLAB tools, Study of transient response analysis of neuromuscular reflex model action by MATLAB tools, Circulatory control model and glucose insulin regulation model by MATLAB tools | |
| Unit-6: Applications of Control theory to physiological systems | 5 hours |
| Applications of Control theory to physiological systems. Time-domain, frequency domain, stability analysis. Biological performance criteria and adaptive control systems. | |

Suggested Readings:

1. “Physiological control systems: Analysis, Simulation and Estimation”, Khoo Michael C.K., Prentice Hall of India Pvt, Ltd, New Delhi
2 “Virtual Bioinstrumentation Biomedical, Clinical and Healthcare applications”, .Olansen Jon B. and Eric Rosow, Prentice Hall PTR, Upper Saddle River, Nj.
3. “Biological Control System analysis”, Milsum John H., McGraw Hill, 1966.

| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | Medical Instrumentation-II | | | | |
| Course Code | BMET 4002 | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

Course Objectives:
Students will understand about the Measurement and Recording of Noninvasive Diagnostic Instrumentation, Basic measuring instruments, Patient monitoring system, Biotelemetry & Respiratory Equipments.

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Measurement and Recording of Noninvasive Diagnostic Instrumentation |
| CO2 | Understand the Basic measuring instruments |
| CO3 | Understand the Patient monitoring system |
| CO4 | Understand the Biotelemetry |
| CO5 | Understand about the Audiometers |
| CO6 | Analyse the Respiratory Equipments |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Measurement and Recording of Noninvasive Diagnostic Instrumentation | 7 hours |
| Measurement and Recording of Noninvasive Diagnostic Instrumentation, Patient Care and Electrical Safety: Principle of ultrasonic measurement, ultrasonic, thermography, elements of intensive care monitoring,X-ray, CT – Scan and MRI, tonometer, dialysis, diathermy, Shock hazards from electrical equipment. | |
| Unit-2: Basic measuring instruments | 7 hours |
| Multimeters – analog and digital multimeters. Frequency and time measurement – analog CRO and digital storage oscilloscope. Medical display systems – single and multichannel displays, nonfade displays, LED and LCD displays. | |
| Unit-3: Patient monitoring system | 7 hours |
| Patient monitoring system–Bed-side monitors, Central station monitors, Computerized arrhythmia monitors, Cardio scope, Ambulatory monitors, Neonatal monitors,Holter monitoring, Infant Warmer, Neonatal Incubator, Infusion pump, syringe pump,Cardiotocograph – Methods of monitoring fetal heart rate | |
| Unit-4: Biotelemetry | 7 hours |
| Biotelemetry – Principles – Types – Single channel and Multichannel – Frequency division and Time division multiplexing, Telestimulation, Telemedicine – Principles and applications | |
| Unit-5: Audiometers | 7 hours |
| Audiometers –Pure tone, Speech and Mask audiometers, Bekesy audiometers, Tympanometers. Hearing aids, Cochlear implants, Ear moulds. Densitometers – Principle and applications. | |
| Unit-6: Respiratory Equipments | 5 hours |
| Respiratory Equipments:Ventilators–Generations–Parameters-Modes of operationsPressure, Flow, volume, cycling, Ventilator terms – ventilator types– Jet ventilators,Humidifier, Nebulizer, Spirometry, Nitric Oxide Therapy,PFT,Plethysmography,Oxymetry –Transmission and Reflection Oxymetry, Fingertip Pulse Oxymeter. | |

Suggested Readings:

1. “Principles of Applied Biomedical Instrumentation”,L.A.Geddes &L.E.Baker, Wiley India Pvt.Ltd, Third Edition,1989.
2. “Handbook of Biomedical Instrumentation”,R.S. Khandpur, Second Edition, Tata McGraw Hill, 2003.
3. “Biomedical Instrumentation”,Shakthi Chatterjee& Aubert Miller, CENGAGE Learning, 2010.
4. “Handbook of Biomedical Instrumentation”,Chanderlekha Goswami, Manglam Publications,

2010.
5. "Medical Instrumentation: Application and Design",John G.Webster, Wiley India Pvt.Ltd, Third Edition, 2002.
6. "CRC Handbook of Clinical Engineering", B. N. Feinberg, CRC Press, 1980.
7. "The Biomedical Engineering Handbook",Joseph D. Bronzino, CRC Press, 1995.

| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | Biomaterials and Artificial Organs | | | | |
| Course Code | BMET 4003 | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

Course Objectives:
Students will understand about the Biomaterials and Artificial Organs

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the basic concept of biomaterials |
| CO2 | Understand the Biocompatibility & toxicological screening of biomaterials |
| CO3 | Understand the implant materials |
| CO4 | Understand the Orthopaedic Implants & Prosthetic Devices |
| CO5 | Understand about the Cardiovascular Implants and Extracorporeal Devices |
| CO6 | Analyze the Sensory Devices & artificial skins functions |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Introduction to biomaterials | 7 hours |
| Introduction: Definition of biomaterials, requirements of biomaterials, classification of biomaterials, Comparison of properties of some common biomaterials. Effects of physiological fluid on the properties of biomaterials. Biological responses (extra and intra-vascular system). Surface properties of materials, physical properties of materials, mechanical properties | |
| Unit-2: Biocompatibility & toxicological screening of biomaterials | 7 hours |
| Definition of biocompatibility, blood compatibility and tissue compatibility. Toxicity tests: acute and chronic toxicity studies (in situ implantation, tissue culture, haemolysis, thrombogenic potential test, systemic toxicity, intracutaneous irritation test), sensitization, carcinogenicity, mutagenicity and special tests. | |
| Unit-3: implant materials | 7 hours |
| Polymeric implant materials, Ceramic implant materials, Composite implant materials, Metallic implant materials | |
| Unit-4: Orthopaedic Implants & Prosthetic Devices | 7 hours |
| Alveolar bone replacements. Orthopedic implants – types of orthopedic function devices, permanent joint replacements, hip joint, bone cement, Artificial limbs, hand and foot, dental prosthesis | |
| Unit-5: Cardiovascular Implants and Extracorporeal Devices | 7 hours |

| | |
|---|---|
| Blood clotting, Blood Rheology, Heart, Aorta, Valves, Lungs, Vascular Implants, Cardiac Pacemaker, Blood Substitutes, Kidney Function. Artificial kidney, Artificial heart-lung machine | |
| Unit-6: Sensory Devices & artificial skins | 5 hours |
| Intraocular Lens and hearing aids, artificial skins | |

Suggested Readings:

1. "Biomedical Engineering Principles, An Introduction to fluid , heat and mass transfer process", Cooney D. O., Marcel Dekker Inc, (1976).
2. "Transport Phenomena is living systems- Biomedical Aspects of Momentum and Man Transport", Lightfoot E. N., John Wiley (1974).
3 "Basic transport phenomena in biomedical engineering", Fournier, Ronald L., Taylor & Francis, 1998.

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|---|---|---|---|---|
| Name of The Course | Medical Informatics | | | |
| Course Code | BMET 4004 | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives:
Students will understand about the Medical Informatics

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the basic concept of Medical Informatics |
| CO2 | Understand the Computerised Patient Record |
| CO3 | Understand the Computers in Clinical Laboratory and Medical Imaging |
| CO4 | Understand the Computer Assisted Medical Decision-Making |
| CO5 | Understand about the Recent Trends In Medical Informatics |
| CO6 | Analyze the Databases And Computer Network |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Introduction to Medical Informatics | 7 hours |
| Introduction - Structure of Medical Informatics –Internet and Medicine -Security issues, Computer based medical information retrieval, Hospital management and informationSystem, Functional capabilities of a computerized HIS, E-health services, HealthInformatics – Medical Informatics, Bioinformatics | |
| Unit-2: Computerised Patient Record | 7 hours |
| Introduction - History taking by computer, Dialogue with the computer, Components and functionality of CPR, Development tools, Intranet, CPR in Radiology- Application serverprovider, Clinical information system, computerized prescriptions for patients | |
| Unit-3: Computers in Clinical Laboratory and Medical Imaging | 7 hours |

| | |
|---|---|
| Automated clinical laboratories-Automated methods in hematology, cytology andhistology, Intelligent Laboratory Information System - Computerized ECG, EEG and EMG, Computer assisted medical imaging- nuclear medicine | |
| Unit-4: Computer Assisted Medical Decision-Making | 7 hours |
| Neuro computers and Artificial Neural Networks application, Expert system –General model of CMD, Computer –assisted decision support system-production rule system cognitive model, semester networks , decisions analysis in clinical medicine-computers in the care of critically patients-computer assisted surgery-designing | |
| Unit-5: Recent Trends In Medical Informatics | 7 hours |
| irtual reality applications in medicine, Computer assisted surgery, Surgical simulation, Telemedicine - Tele surgery computer aids for the handicapped, computer assisted Instrumentation in Medical Informatics - Computer assisted patient education and health Medical education and health care information | |
| Unit-6: Databases And Computer Network | 5 hours |
| Basics of databases- Relational, distributed and other types of databases, Integrity and security of databases, DBMS. Popular databases available in medical related applications. Basics of Computer networks- types and topologies. | |

Suggested Readings:

1. R.D.Lele "*Computers in medicine progress in medical informatics"*, Tata McGraw Hill Publishing computers Ltd, 2005, New Delhi.
2. Mohan Bansal, "*Medical informatics"* Tata McGraw Hill Publishing computers Ltd, 2003 New Delhi.

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|---|---|---|---|---|
| Name of The Course | Data structure using C | | | |
| Course Code | BMET 4005 | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives:

Students will understand about the Data structure using C

Course Outcomes:

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Data structure Introduction |
| CO2 | Understand the Stacks & , Operations on Queue |
| CO3 | Understand the Tree Traversal algorithms |
| CO4 | Understand the Graphs & algorithm |
| CO5 | Understand about the Searching & Sorting |
| CO6 | Analyze the Search Trees |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Data structure Introduction | 7 hours |

| | |
|---|---|
| Introduction: Basic Terminology, Elementary Data Organization, Algorithm, Efficiency of an Algorithm, Time and Space Complexity, Asymptotic notations: Big-Oh, Time-Space trade-off. Abstract Data Types (ADT) Arrays: Definition, Single and Multidimensional Arrays, Representation of Arrays: Row Major Order, and Column Major Order, Application of arrays, Sparse Matrices and their representations. Linked lists: Array Implementation and Dynamic Implementation of Singly Linked Lists, Doubly Linked List, Circularly Linked List, Operations on a Linked List. Insertion, Deletion, Traversal, Polynomial Representation and Addition, Generalized Linked List . | |
| Unit-2: Stacks & , Operations on Queue | 7 hours |
| Stacks: Abstract Data Type, Primitive Stack operations: Push & Pop, Array and Linked Implementation of Stack in C, Application of stack: Prefix and Postfix Expressions, Evaluation of postfix expression, Recursion, Tower of Hanoi Problem, Simulating Recursion, Principles of recursion, Tail recursion, Removal of recursion Queues, Operations on Queue: Create, Add, Delete, Full and Empty, Circular queues, Array and linked implementation of queues in C, Dequeue and Priority Queue. | |
| Unit-3: Tree Traversal algorithms | 7 hours |
| Trees: Basic terminology, Binary Trees, Binary Tree Representation: Array Representation and Dynamic Representation, Complete Binary Tree, Algebraic Expressions, Extended Binary Trees, Array and Linked Representation of Binary trees, Tree Traversal algorithms: Inorder, Preorder and Postorder, Threaded Binary trees, Traversing Threaded Binary trees, Huffman algorithm. | |
| Unit-4: Graphs & algorithm | 7 hours |
| Graphs: Terminology, Sequential and linked Representations of Graphs: Adjacency Matrices, Adjacency List, Adjacency Multi list, Graph Traversal : Depth First Search and Breadth First Search, Connected Component, Spanning Trees, Minimum Cost Spanning Trees: Prims and Kruskal algorithm. Transistive Closure and Shortest Path algorithm: Warshal Algorithm and Dijikstra Algorithm, Introduction to Activity Networks | |
| Unit-5: Searching & Sorting | 7 hours |
| Searching : Sequential search, Binary Search, Comparison and Analysis Internal Sorting: Insertion Sort, Selection, Bubble Sort, Quick Sort, Two Way Merge Sort, Heap Sort, Radix Sort, Practical consideration for Internal Sorting. | |
| Unit-6: Search Trees | 5 hours |
| Search Trees: Binary Search Trees(BST), Insertion and Deletion in BST, Complexity of Search Algorithm, AVL trees, Introduction to m-way Search Trees, B Trees & B+ Trees . Hashing: Hash Function, Collision Resolution Strategies Storage Management: Garbage Collection and Compaction. | |

Suggested Readings:

1. Aaron M. Tenenbaum,YedidyahLangsam and Moshe J. Augenstein “Data Structures Using C and C++”, PHI Learning Private Limited, Delhi India

2. Horowitz and Sahani, “Fundamentals of Data Structures”, Galgotia Publications Pvt Ltd Delhi India.

3. A.K. Sharma ,Data Structure Using C, Pearson Education India.

4. Rajesh K. Shukla, “Data Structure Using C and C++” Wiley Dreamtech Publication.

5. Lipschutz, “Data Structures” Schaum’s Outline Series, Tata Mcgraw-hill Education (India) Pvt. Ltd 6. Michael T. Goodrich, Roberto Tamassia, David M. Mount “Data Structures and Algorithms in C++”, Wiley India

# Elective-II

| | |
|---|---|
| Name of The Course | Biomechanics |
| Course Code | BMET 4006 |

| | | | | | |
|---|---|---|---|---|---|
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

Course Objectives:
Students will understand about the Biomechanics

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Introduction to Fluid Mechanism |
| CO2 | Understand the Flow Analysis of Velocity and Pressure Gradient |
| CO3 | Understand the Flow Dynamical Study of Circulating System |
| CO4 | Understand the Soft Tissue & Lungs Mechanics |
| CO5 | Understand about the Orthopaedic Mechanics |
| CO6 | Analyze the Cochlear Mechanics |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Introduction to Fluid Mechanism | 7 hours |
| asic laws governing conservation of mass, Newton's Law, Hooke's Law, momentum and energy, laminar flow, Newtonian and Non-Newtonian Fluid, Viscoelastic fluid, Couette flow and Hagen-Poiseville equation, turbulent flow. | |
| Unit-2: Flow Analysis of Velocity and Pressure Gradient | 7 hours |
| Arterial impedance relating pulse pressure and flow rate, mechanism and transport in microcirculation, microcirculatory flow, Transcapillary fluid movements in systemic circulation, physiological factors controlling blood pressure, Heart valves. | |
| Unit-3: Flow Dynamical Study of Circulating System | 7 hours |
| Heart and blood vessels, Ventricular pressure, volume, ECG time based cyclic variation. Determination of ventricular wall diastolic, systolic modules verses stress properties and their physiological connotation, Intra-ventricular blood | |
| Unit-4: Soft Tissue & Lungs Mechanics | 7 hours |
| Pseudo-elasticity, Nonlinear stress- strain relationship, Structural and functional properties of skin, ligaments and tendon, Muscle in terms of its elastic and contractile element parameters; Lung structure and function, methods of determining lung pressure and volume, airway resistance and conductance | |
| Unit-5: Orthopaedic Mechanics | 7 hours |
| Mechanical properties of Cartilage, Diffusion properties of articular cartilage, Mechanical properties of bone, Kinetics and kinematics of joint, Lubrication of joints, Analysis of force in orthopaedic implants | |
| Unit-6: Cochlear Mechanics | 5 hours |
| Passive Models, Active Models, Vestibular Mechanics, Otolith Distributed Parameter model, Non- Dimensionalisation of the Motion Equation, Otolith Transfer Function and Frequency Response, Semicircular Canal Distributed Parameter model and its Frequency Response | |

Suggested Readings:

1. Y.C. Fung : Biomechanics –Circulation, Springer Verlag, 1997.
2. Susan J. Hall : Basic Biomechanics l, TMH, 2002.
3. Ozkay & Margareta Nordin: Fundamentals of Biomechanics, Springer Verlag, 1999.
4. Y.C. Fung :Biomechanics-Mechanical Properties of Living tissues, Springer Verlag, 1981
5. Dawson and Right :Introduction to biomechanics of joints and joint replacement, Mechanical Engg. Publication Ltd. 1989.
6. Jacob Kline :Handbook of Biomedical Engineering, Academic Press Inc. 1988

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|---|---|---|---|---|---|
| Name of The Course | Microprocessors and MicroControllers | | | | |
| Course Code | BMET 4007 | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

Course Objectives:
Students will understand about the Microprocessors and MicroControllers

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the 8086 Architecture |
| CO2 | Understand the Instruction Set and Assembly Language Programming of 8086 |
| CO3 | Understand the I/O Interface & Communication Interface |
| CO4 | Understand the Interfacing with advanced devices |
| CO5 | Understand about the Introduction to Microcontrollers |
| CO6 | Analyze the The AVR RISC microcontroller architecture |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: 8086 Architecture | 7 hours |
| Introduction to 8085 Microprocessor, 8086 Architecture-Functional diagram. Register Organization, Memory Segmentation. Programming Mode!. Memory addresses. Physical memory organization. Architecture of 8086, signal descriptions of 8086- common function signals. Minimum and Maximum mode signals. Timing diagrams. Interrupts of 8086. | |
| Unit-2: Instruction Set and Assembly Language Programming of 8086 | 7 hours |
| Instruction formats, addressing modes, instruction set, assembler directives, macros, simple programs involving logical, branch and call instructions, sorting, evaluating arithmetic expressions, string manipulations | |
| Unit-3: I/O Interface & Communication Interface | 7 hours |
| 8255 PPI various modes of operation and interfacing to 8086. Interfacing keyboard, display, stepper motor interfacing, D/A and A/D converter; Serial communication standards, Serial data transfer schemes. 8251 USART architecture and interfacing. RS- 232. IEEE-4-88, Prototyping and trouble shooting | |
| Unit-4: Interfacing with advanced devices | 7 hours |

| | |
|---|---|
| Memory interfacing to 8086, Interrupt structure of 8086, Vector interrupt table, Interrupt service routine. Introduction to DOS and BIOS interrupts, Interfacing Interrupt Controller 8259 DMA Controller 8257 to 8086. | |
| Unit-5: Introduction to Microcontrollers & 8051 Real Time Control | 7 hours |
| Overview of 8051 microcontroller. Architecture. I/O Ports. Memory organization, addressing modes and instruction set of 8051, simple program; Interrupts, timer/ Counter and serial communication, programming Timer Interrupts, programming external hardware interrupts, programming the serial communication interrupts, programming 8051 timers and counter | |
| Unit-6: The AVR RISC microcontroller architecture | 5 hours |
| Introduction, AVR Family architecture, Register File, The ALU. Memory access and Instruction execution. I/O memory. EEPROM. I/O ports. Timers. UART. Interrupt Structure | |

Suggested Readings:

1. D. V. Hall. Micro processors and Interfacing, TMGH. 2'1 edition 2006.
2. Kenneth. J. Ayala. The 8051 microcontroller , 3rd edition, Cengage learning, 2010

# Semester V

| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | Research Methodology & Biostatistics | | | | |
| Course Code | BMET 5001 | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 4 | 0 | 0 | 4 |

Course Objectives:
Students will get exposure about Research Methodology & Biostatistics

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Research |
| CO2 | Understand about the Research Design |
| CO3 | Understand about the Research Report and ethics |
| CO4 | Understand about the Sampling methods |
| CO5 | Understand about the Measures of central tendency |
| CO6 | Understand about Hypothesis testing |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Content:

| | |
|---|---|
| Unit-1: Introduction to Research | 8 hours |
| Research definition, types, advantage and significance. Introduction to research methods, identifying research problem, definition, objectives, role, scope in biotech research, process of research, limitations & types | |
| Unit-2: Research Design | 7 hours |
| Concept of Interdisciplinary Research, Procedures in research. Types of Research Design: Experimental/Interventional research, Quasi-experimental studies, Observational research. Sources | |

| | |
|---|---|
| of Experimental Errors. Survey research: Types of surveys- CATI, CAPI, Mail, Email, Face-to-face, Questionnaire | |
| Unit-3: Research Report and ethics | 5 hours |
| Type of research report- Research, review, case report, manuscript, monograph, book chapters. Structure of Research Reports. Quoting of reference and bibliography using reference management tools. Ethical issues in research, plagiarism. | |
| Unit-4: Sampling methods | 5 hours |
| Sampling methods, Advantages and Limitation, Sampling process, Types of Sampling, Probability and Non Probability sampling techniques, sampling errors, Data collection Primary and secondary data, Collection and validation. | |
| Unit-5: Measures of central tendency | 8 hours |
| Measures of central tendency- Mean, Median, Mode; Measures of dispersion- Range, Mean deviation and Coefficient of variation, Standard deviation, Standard error; Correlation and regression; Statistical inference- Hypothesis testing, Significance level, Confidence interval, t-test, z-test. Test of significance for large and small samples; Parametric tests; Non parametric tests; Experimental design, Use of biostatistic softwares. | |
| Unit-6: Hypothesis testing | 7 hours |
| Null hypothesis and test of significance (t-test, paired t-test, Analysis of variance, Analysis of covariance, Coefficient of Variation, chi-square test, Fischer exact, Mann-Whitney, Wilcoxin, McNeman test, Kruskal Wallis. | |

Suggested Readings:


21. Graziano AM, Raulin ML. Research methods: A process of inquiry. HarperCollins College Publishers; 1993.
22. C.R. Kothari : Research Methodology, New Age International Publishers
23. Bouma GD, Ling R, Wilkinson L. The research process. Oxford: Oxford University Press; 1993 Mar 30.
24. Dawson B, Trapp RG. Basic and clinical biostatistics. Singapore. 2004;2001:141-2


| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | Medical signal & Image processing | | | | |
| Course Code | BMET 5002 | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

Course Objectives:
Students will understand about the Medical signal & Image processing

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the |
| CO2 | Understand the Biomedical Signals |
| CO3 | Understand the Fundamentals of Deterministic Signal Processing |
| CO4 | Understand the Fundamentals of Deterministic Image Processing |
| CO5 | Understand about the Probability and Random Signals |
| CO6 | Analyze the Image Segmentation and Registration |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Biomedical Signals | 7 hours |
| ECG: Cardiac electrophysiology, relation of electrocardiogram (ECG) components to cardiac events, clinical applications. Speech Signals: The source-filter model of speech production, spectrographic analysis of speech. Speech Coding: Analysis-synthesis systems, channel vocoders, linear prediction of speech, linear prediction vocoders. | |
| Unit-2: Biomedical Image | 7 hours |
| Imaging Modalities: Survey of major modalities for medical imaging: ultrasound, X-ray, CT, MRI, PET, and SPECT. MRI: Physics and signal processing for magnetic resonance imaging. Surgical Applications: A survey of surgical applications of medical image processing. | |
| Unit-3: Fundamentals of Deterministic Signal Processing | 7 hours |
| Data Acquisition: Sampling in time, aliasing, interpolation, and quantization. Digital Filtering: Difference equations, FIR and IIR filters, basic properties of discrete-time systems, convolution. DTFT: The discrete-time Fourier transform and its properties. FIR filter design using windows. DFT: The discrete Fourier transform and its properties, the fast Fourier transform (FFT), the overlap-save algorithm, digital filtering of continuous-time signals. | |
| Unit-4: Fundamentals of Deterministic Image Processing | 7 hours |
| Sampling Revisited: Sampling and aliasing in time and frequency, spectral analysis. Image processing I: Extension of filtering and Fourier methods to 2-D signals and systems. Image processing II: Interpolation, noise reduction methods, edge detection, homomorphic filtering. | |
| Unit-5: Probability and Random Signals | 7 hours |
| PDFs: Introduction to random variables and probability density functions (PDFs). Classification: Bayes' rule, detection, statistical classification. Estimating PDFs: Practical techniques for estimating PDFs from real data. Random signals I: Time averages, ensemble averages, autocorrelation functions, crosscorrelation functions. Random signals II: Random signals and linear systems, power spectra, cross spectra, Wiener filters. Blind source separation: Use of principal component analysis (PCA) and independent component analysis (ICA) for filtering | |
| Unit-6: Image Segmentation and Registration | 5 hours |
| Image Segmentation: statistical classification, morphological operators, connected components.<br>Image Registration I: Rigid and non-rigid transformations, objective functions.<br>Image Registration II: Joint entropy, optimization methods. | |

Suggested Readings:


1. Quatieri, T. F. Discrete-Time Speech Signal Processing: Principles and Practice. Upper Saddle River, NJ: Prentice-Hall, 2001. ISBN: 9780132429429.
2. Lim, J. S. Two-Dimensional Signal and Image Processing. Upper Saddle River, NJ: Prentice Hall, 1989. ISBN: 9780139353222.
3. Gonzalez, R., and R. E. Woods. Digital Image Processing. 2nd ed. Upper Saddle River, NJ: Prentice-Hall, 2002. ISBN: 9780201180756.


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|---|---|---|---|---|---|
| Name of The Course | Tissue Engineering & Microfluidics | | | | |
| Course Code | BMET 5003 | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

Course Objectives:
Students will understand about the Tissue Engineering & Microfluidics

Course Outcomes:

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Introduction to tissue engineering |
| CO2 | Understand the Cell-extracellular matrix interactions |
| CO3 | Understand the Cell and tissue culture |
| CO4 | Understand the tissue engineering case studies |
| CO5 | Understand about the Microfabrication techniques |
| CO6 | Analyze the Microfluidics components |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Introduction to tissue engineering | 5 hours |
| Cells as therapeutic Agents with examples, Cell numbers and growth rates. Tissue organization, Tissue Components, Tissue types, Functional subunits. Tissue Dynamics, Dynamic states of tissues, Homeostasis in highly prolific tissues and Tissue repair. Angiogenesis. | |
| Unit-2: Cell-extracellular matrix interactions | 5 hours |
| Cell-extracellular matrix interactions - Binding to the ECM, Modifying the ECM, Malfunctions in ECM signaling. Direct Cell-Cell contact - Cell junctions in tissues, malfunctions in direct cell-cell contact signaling. Response to mechanical stimuli. | |
| Unit-3: Cell and tissue culture | 6 hours |
| Cell and tissue culture - types of tissue culture, media, culture environment and maintenance of cells in vitro, cryopreservation; Basis for Cell Separation, characterization of cell separation, methods of cell separation. | |
| Unit-4: tissue engineering case studies | 7 hours |
| Bioreactors for Tissue Engineering.; In vivo cell & tissue engineering case studies: Artificial skin, Artificial blood vessels. In vivo cell & tissue engineering case studies: Artificial pancreas, Artificial liver. Regeneration of bone, muscle. Nerve regeneration. | |
| Unit-5: Microfabrication techniques | 7 hours |
| Materials, Clean room,Silicon crystallography, Miller indices. Oxidation, photolithography- mask, spin coating, exposure and development,Etching,Bulk and Surface micromachining, Wafer bonding. Polymer microfabrication,PMMA/COC/PDMS substrates, micromolding, hot embossing, fluidic interconnections. | |
| Unit-6: Microfluidics components | 10 hours |
| Micropumps, Check-valve pumps,Valve-less pumps,Peristaltic pumps, Rotary pumps, Centrifugal pumps, Ultrasonic pump, EHD pump, MHD pumps. Microvalves,Pneumatic valves, Thermopneumatic valves, Thermomechanical valves,Piezoelectric valves,Electrostatic valves,Electromagnetic valves, Capillary force valves. Microflow sensors, Differential pressure flow sensors, Drag force flow sensors, Lift force flow sensors, Coriolis flow sensors, Thermal flow sensors. Micromixers,Physics of mixing,Pe-Re diagram of micromixers, Parallel lamination,Sequential lamination, Taylor-Aris dispersion. Droplet generators,Kinetics of a droplet, Dynamics of a droplet, In-channel dispensers, T-junction and Cross-junction, Droplet formation, breakup and transport. Microparticle separator, principles of separation and sorting of microparticles, design and applications. Microreactors, Design considerations, Liquid-phase reactors, PCR, Design consideration for PCR reactors | |

Suggested Readings:

1. Nguyen, N. T., Werely,S. T., Fundamentals and applications of Microfluidics,Artech house Inc., 2002.

2. Bruus, H., Theoretical Microfluidics, Oxford University Press Inc., 2008.
3. Madou, M. J., Fundamentals of Microfabrication, CRC press, 2002.
4. Tabeling,P., Introduction to microfluidics, Oxford University Press Inc., 2005
5. Kirby,B.J., Micro- and Nanoscale Fluid Mechanics: Transport in Microfluidic Devices,Cambridge University Press, 2010.
6. Colin,S., Microfluidics, John Wiley & Sons, 2009.

| Name of The Course | Bioethics and Biosafety | | | |
|---|---|---|---|---|
| Course Code | BMET 5004 | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives:
To understand the Bioethics and Biosafety
Course Outcomes
On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Understand the Conceptual foundations of biomedical ethics |
| CO2 | Analyze the Ethics in health care |
| CO3 | Examine the Ethical dimensions of GMO & Bioweapons |
| CO4 | Understand the Biosafety regulations and competent authorities |
| CO5 | Analyze the Principles and components of containment |
| CO6 | Examine the Operational Guides on Containment |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Content

| |
|---|
| Unit-1 Conceptual foundations of biomedical ethics 7 hours |
| Principlism; Deontology; Consequentialism/Utilitarianism; Communitarianism; Virtue ethics; Ethics of Care; Human Rights |
| Unit-2 Ethics in health care 7 hours |
| Ethical dimensions of palliative care and end-of-life care; Reproductive health ethics; Ethical issues in global health; Ethics and the pharmaceutical industry; Ethical issues in rural health care |
| Unit-3 Ethical dimensions of GMO & Bioweapons 7 hours |
| Ethical dimensions of genetic and genome-based research; Ethical dimensions of research involving bioweapons; Ethics in gene therapy, germ line, somatic, embryonic and adult stem cell research. |
| Unit-4 Biosafety regulations and competent authorities 7 hours |
| Recombinant DNA Advisory Committee (RDAC); Review Committee on Genetic Manipulation (RCGM); Institutional Biosafety Committee (IBSC); Genetic Engineering Appraisal Committee (GEAC); State Biotechnology Co-ordination Committee (SBCC); District Level Committee (DLC) |
| Unit -5 Principles and components of containment 5 hours |
| Factors in Containment: Physical Containment; Biological Containment; Laboratory Monitoring; Health and Medical Surveillance; Decontamination and Disposal; Emergency Procedures; |
| Unit -6 Operational Guides on Containment 7 hours |

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|---|
| Microbiological Biosafety Level (BSL) Facilities; Containment For Large Scale Operations Of Genetically Engineered (GE) Microorganisms; Animal Biosafety Level Facilities; Containment requirement for import, export and exchange |

Suggested Readings:

1. Beier, F.K., Crespi, R.S. and Straus, T. Biotechnology and Patent protection-Oxford and IBH Publishing Co. New Delhi
2. Bioethics and Biosafety- M.K. Sateesh
3. Bioethics and Biosafety- Rajmohan

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|---|---|---|---|---|---|
| Name of The Course | Biopotentials | | | | |
| Course Code | BMET 5005 | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

Course Objectives:

To impart the complete knowledge of Electrophysiology which forms the base of Bioinstrumentation i.e. how Bioelectric signals are generated, propagated, transduced, amplified and recorded. Proper recording of the bioelectric signals help in diagnosis of the diseases.

Course Outcomes

On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Understanding of bioelectric phenomena |
| CO2 | Understanding of Interaction of signals |
| CO3 | Understanding of Electrical circuit model of the membrane |
| CO4 | Analyze the ECG EMG and EEG |
| CO5 | Examine the Central nervous system and neuro-control mechanisms |
| CO6 | Analyze the Receptors as biological transducers |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Content:

| |
|---|
| Unit-1: Introduction to bioelectric phenomena 7 hours |
| Bioelectric phenomena, Neurons and Synapse; Generation, Transmission and Propagation of signals in nervous systems – Resting Potential, Action Potential, Synaptic Potential. |
| Unit-2: Interaction of signals 7 hours |
| EPSP (Excitatory Post Synaptic Potentials) and IPSP (Inhibitory Post Synaptic Potentials); Interaction of signals to control various functions and reflexes of body. |
| Unit-3: Electrical circuit model of the membrane 7 hours |
| Electrical circuit model of the bio-membrane, The Laws of stimulation and conduction of nerve impulse. |
| Unit-4 : ECG EMG and EEG 7 hours |
| Electrocardiography (ECG) and its diagnostic applications– Generation and propagation of cardiac impulse, SA node as Pacemaker, Ectopic Pacemakers, PQRST Wave Pattern. Various cardiographic |

| |
|---|
| leads (Limb leads, Chest leads), Vectorial analysis of normal and diseased heart Electrophysiological signals- EMG, Brain potentials and their generation, Propagation, recording and diagnostic applications. |
| Unit-5: Central nervous system and neuro-control mechanisms 7 hours |
| Nervous system, Neuro-Anatomy in brief, Neural circuits for processing information, Central Nervous System, Peripheral Nervous System, Ventricle and Cerebrospinal Fluid, Neuro control Mechanisms |
| Unit-6 Receptors as biological transducers 5 hours |
| Receptors as biological transducers, Transduction and Amplification in receptors, Properties of receptors. |

Suggested Readings:

10. Introduction to Neurobiophysics, Vasilescu, S.G. Margineanu, Abascus Press, Tunbridge Wells, Vent.
11. Text Book of Medical Physiology, Guyton A.C. and J.E. Hall, Harcourt India Pvt. Ltd.
12. Anatomy and Physiology, Ross and Wilson, Churchill Livingstone.

# Elective-III

| | | | | | |
|---|---|---|---|---|---|
| Name of The Course | Linear Integrated Circuits | | | | |
| Course Code | BMET 5006 | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

Course Objectives:
Students will understand about the Linear Integrated Circuits

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Integrated Circuits |
| CO2 | Understand the Operation Amplifier |
| CO3 | Understand the OP-AMP APPLICATIONS |
| CO4 | Understand the Active Filters, Oscillators And Regulators |
| CO5 | Understand about the TIMERS & PHASE LOCKED LOOPS |
| CO6 | Analyze the D-A AND A- D CONVERTERS |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Integrated Circuits | 7 hours |
| Classification, chip size and circuit complexity, Fundamentals of Monolithic IC technology, basic planar processes, Fabrication of a typical circuit, Active and passive components of ICs, fabrication of FET, Thin and thick film technology. | |
| Unit-2: Operation Amplifier | 7 hours |

| | |
|---|---|
| Basic information of Op-amp, ideal and practical Op-amp, Op-amp characteristics, 741 op-amp and its features, modes of operation-inverting, noninverting, differential mode | |
| Unit-3: OP-AMP APPLICATIONS | 7 hours |
| Basic application of Op-amp, instrumentation amplifier, ac amplifier, V to I and I to V converters, Precision rectifiers, log and antilog amplifiers, sample & hold circuits, multipliers and dividers, Differentiators and Integrators, Comparators, Schmitt trigger, Multivibrator, Triangular wave generator. | |
| Unit-4: Active Filters, Oscillators And Regulators | 7 hours |
| Introduction-Low pass and High pass filters- Design of first and second order Butterworth lowpass and high pass filters Band pass, Band reject and all pass filters- Oscillator types and principle of operation – RC, Wien bridge oscillators triangular, saw-tooth, square wave and VCO- Introduction to voltage regulators, features of 723, Three Terminal IC regulators- DC to DC Converter- Switching Regulators-UPS-SMPS. | |
| Unit-5: Timers & Phase Locked Loops | 7 hours |
| Introduction to 555 timer, functional diagram, monostable and astable operations and applications, Schmitt Trigger. PLL - introduction, block schematic, principles and description of individual blocks of 565-PLL applications, Analog and digital phase detectors. | |
| Unit-6: D-A AND A- D CONVERTERS | 5 hours |
| Introduction, basic DAC techniques, weighted resistor DAC, R-2R ladder DAC, Different types of ADCs - parallel comparator type ADC, counter type ADC, successive approximation ADC, dual slope ADC and Sigma delta ADC. DAC and ADC specifications. DAC 0800 and ADC 0804 pin diagram and applications | |

Suggested Readings:

1. D. Roy Chowdhury, “Linear Integrated Circuits” New Age International (p) Ltd, 2nd Ed., 2003.
2. R.F. Coughlin & Fredrick F. Driscoll. Operational Amplifiers & Linear Integrated Circuits, PHI, 6th Edition, 2003
3. Ramakanth A. Gayakwad, Op-Amps & Linear ICs –PHI, 4th Edition 2004.

| **Name of The Course** | **Drug Discovery and Development** | | | |
|---|---|---|---|---|
| **Course Code** | **BMET 5007** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives:
Students will get exposure about Drug Discovery and Development
Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand about the basic concepts of Drug Discovery and Development |
| CO2 | Understand about the Pre-Clinical Studies |
| CO3 | Understand about Bioassays |
| CO4 | Understand about the Drug designing |
| CO5 | Understand about the Methods and Process of Drug discovery |
| CO6 | Understand about the Non Clinical Drug Development |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Content:

| | |
|---|---|
| Unit-1: Introduction to Drug development | 7 hours |
| Need for a new Drug, Target identification, lead identification, Sources of new drugs: synthetic, natural, endogenous, peptides; compounds for screening as a potential drug, Drug Discovery & Drug development process. In vivo, in vitro and in silico studies. Animal models of diseases. | |
| Unit-2: Pre-Clinical Studies | 7 hours |
| Importance of Pre-Clinical studies, Steps involved in Pre-clinical studies, Types of Pre-Clinical Studies, Introduction to toxicology, Organ specific toxicity, Toxicity Studies. | |
| Unit-3: Bioassays | |
| Bioassays; Biochemical, Molecular, Behavioural & Physiological parameter analysis, Pharmacokinetics, Pharmacology, Pharmacodynemics, Tissue distribution study | |
| Unit-4: Drug designing | 7 hours |
| Drug design-Ligand based, Structure based, target-centered drug design: DNA, RNA and Protein based drug designing, Structure Activity Relationship (SAR), Quantitative Structure Activity Relationship (QSAR), Computer assisted drug designing (CADD) | |
| Unit-5: Methods and Process of Drug discovery | 7 hours |
| High Through Put Screening (HTS): Introduction, Advantages and Disadvantages, Uses, Methodology; Combinatorial Chemistry, methods and processes; Lead optimization techniques | |
| Unit-6: Non Clinical Drug Development | 5 hours |
| GLP, GMP, GCP; submission of IND, NDA, ANDA | |

Suggested Readings


11 Preclinical Drug Development, Edited by Mark Rogge, David R. Taft, Second Edition, 25th Sep 2009.
12 Hill RG. Drug Discovery and Development-E-Book: Technology in Transition. Elsevier Health Sciences; 2012 Jul 20.
13 Choudhary MI, Thomsen WJ. Bioassay techniques for drug development. CRC Press; 2001 Oct 4.
14 Klebe G. Drug Design: Methodology, concepts, and mode-of-action. Heidelberg, Germany: Springer; 2013 Jul 10.
15 Armstrong JD, Hubbard RE, Farrell T, Maiguashca B, editors. Structure-based drug discovery: an overview. Royal Society of Chemistry; 2006


# Semester VI

| **Name of The Course** | **Biophysics & Biochemistry** | | | |
|---|---|---|---|---|
| **Course Code** | **BMET 6001** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| L | T | P | C | |
| 3 | 0 | 0 | 3 | |

Course Objectives:
Students will understand about the Biophysics & Biochemistry

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Biological principles |
| CO2 | Understand the Bioelectricity |
| CO3 | Understand the Electrical stimulus & Biophysical activity |
| CO4 | Understand the Radioactivity |
| CO5 | Understand about the Macromolecules |
| CO6 | Analyze the Enzymes and Nucleic acids |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Biological principles | 7 hours |
| Composition & properties of the cell membrane, membrane transports, permeability Coefficient & partition coefficient, body fluids, electrolytes, acid-base balance, blood viscosity and Newtonian nature, colloids, filtration, diffusion, osmosis, dialysis, ultrafiltration, ultracentrifugation, cellular fractionation, electrophoresis, plasmapherosis, radioimmunoassay, Photochemical reaction, law of photochemistry, fluorescence and phosphorescence | |
| Unit-2: Bioelectricity | 7 hours |
| Membrane Potential, Local and propagator types, Diffusion potential, phase boundary potentials, Generator Potentials, compound Action Potentials (AP), Propagation of AP, factors influencing propagation of AP, biosignal and types, Electrical properties of excitable membranes, Membrane Capacitance, Resistance, conductance, dielectric properties of membrane, space and time constant for excitable membrane, equivalent electrical circuit diagram for excitable membranes and neural membranes | |
| Unit-3: Electrical stimulus & Biophysical activity | 7 hours |
| Stimuli, Receptor potential, pacemaker potential, strengthduration relationship, skin impedance, total body impedance, impedances at high frequencies, patient safety, electrical shock and hazards, leakage current, different wave forms & their characteristics. waveform and significance, | |
| Unit-4: Radioactivity | 7 hours |
| Ionizing radiations, U-V & I-R radiations, Production of radioisotopes & their use in biomedical research, Radioactive decays, Half life period, Linear Energy Transfers (LET), Relative Biological Efficiency (RBE) and Interaction of radiation with-matter | |
| Unit-5: Macromolecules | 7 hours |
| Classification and functions of carbohydrates, glycolysis, TCA cycle, ATP sysnthesis, Blood Sugar analysis and glucose tolerance test, Classification and functions of proteins, architecture of proteins, Classification of amino acids, Oxidative and non oxidative deamination, transamination, decarboxylation, urea cycle, Purification/separation of proteins, Classification and functions of lipids, biosynthesis of long chain fatty acids, oxidation and degradation of fatty acids. | |
| Unit-6: Enzymes and Nucleic acids | 5 hours |
| Chemical nature and broad classification of enzymes, M-M-Kinetics, Isozymes and Allosteric enzymes, Isolation techniques, Structure of DNA, Genetic code, Recombinant DNA, Transcription & Translation, Reverse Transcription, Replication. | |

Suggested Readings:

1. Radiation Biophysics, Second Edition - by Edward L. Alpen - Academic Press; 2 edition
2. Bio-Physics – Roland Glaser- Springer; 2nd printing edition (November 23, 2004)
3. Text book of Medical Physiology- Guyton
4. The Biomedical Engineering Hand Book- 3rd Ed- (Biomedical Engineering Fundamentals) - Joseph D.Bronzino – CRC –Tylor-Francis – 2006 (Section- III – Bio-Electrical Phenomena)
5. Lehninger Principles of Biochemistry, Fourth Edition - by David L. Nelson & Michael M.Cox , - W. H.Freeman; 4 edition (April 23, 2004)
6. Fundamentals of Biochemistry: Life at the Molecular Level - by Donald J. Voet , Judith G. Voet & Charlotte W. Pratt. - Wiley; 2 edition (March 31, 2005)

| **Name of The Course** | **Automation And Quality Control In Biomedical Engineering** |
|---|---|

| **Course Code** | **BMET 6002** | | | |
|---|---|---|---|---|
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives:
Students will understand about the Automation and Quality Control in Biomedical Engineering

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Robotic Surgery |
| CO2 | Understand the Mobile Robotics |
| CO3 | Understand the Advanced Robotics systems |
| CO4 | Understand the Biomedical Applications of Medical Robotics |
| CO5 | Understand about the Quality Control |
| CO6 | Analyze the Need for Standardization |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Robotic Surgery | 7 hours |
| Surgical Robots – Types, Advances and Applications. Technologies involved in Robotic Surgery – Sensors, Actuators, Micromechanics, Communication control, Virtual Reality and Artificial Intelligence. Application of Intelligent tools for Robotic systems design, Integration of Electronics and Communication systems with Human nerve network. | |
| Unit-2: Mobile Robotics | 7 hours |
| Architecture of Advanced Mobile Robotics, Actuator design, Navigation, Obstacle avoidance, Sensors and Vision systems. Legged Robotic devices, Control of Mobile Robots in Semi structured environment | |
| Unit-3: Advanced Robotics systems | 7 hours |
| Control, Instrumentation – Navigation – Route planning –Autonomous operation – Haptic interface – Haptic feedback in systems design – System Architecture – Data fusion – System integration, Advances in Micromechatronics. Robotic systems: Robotic Radio surgery system, Computer assisted surgery and Rehabilitation Robotics in Virtual environment | |
| Unit-4: Biomedical Applications of Medical Robotics | 7 hours |
| Nerve cell repair using Micromechatronics, Micro and Nanodevices for targeted delivery of medicines to tumour sites and diagnosis using navigable biosensors, Surgeries performed using robotic systems– Mitral valve Surgery and minimally invasive surgeries, Surgical procedures in General surgery, Neurology, Urology, Gastroenterology, Cardiology, Orthopedics, Pediatrics and Radio surgery | |
| Unit-5: Quality Control | 7 hours |
| Quality control tools, Problem solving methodologies, New Management Tools, Quality policy development, Quality function development, designing for Quality, Manufacturing for Quality | |
| Unit-6: Need for Standardization | 5 hours |
| Regional, National, International Standardization, Methods for Testing Standardization, Maintenance of Standardization & Recalibration, Food and Drug Administration Regulations | |

Suggested Readings:

1. *"Advanced Robotics and Intelligent Machines",* J.O.Roy, Darwin G.Caldwell, D.G.Campbell, Institution of Electrical Engineers, 1996.
2. *"Computer Vision, Virtual Reality and Robotics in Medicine",* Nicholas Ayache Springer-Verlag, 1993.
3. *"Robotics Research",* Raymond A.Jarvis, Alexander Zelinsky Springer, 2003.
4. *"Embedded Robotics",* Thomas Braunl Springer, 2003.
5. *"Sensor Based Intelligent Robots"*, Gregory D.Hager, H.I.Christensen, Horst Bunke, Rolf Klein Springer, 2002.
6. *"Primer of Robotic and Telerobotic Surgery",* Garth H.Ballantyne, Jacques Marescaux, Pier Cristoforo Giulianotti Williams & Wilkins, 2004.

| **Name of The Course** | **Virtual Instrumentation Design For Medical Systems** | | | |
|---|---|---|---|---|
| **Course Code** | **BMET 6004** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives:
Students will understand about the Virtual Instrumentation Design For Medical Systems

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Review of Virtual Instrumentation |
| CO2 | Understand the G Programming |
| CO3 | Understand the Programming Structure & Techniques |
| CO4 | Understand the Hardware Overview |
| CO5 | Understand about the Data Acquisition Basics |
| CO6 | Analyze the principle of Analysis Tools |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| Unit-1: Review of Virtual Instrumentation | 7 hours |
|---|---|
| General functional description of a digital instrument - block diagram of a virtual instrument - physical quantities and analog interfaces - hardware and software - user interfaces - advantages of virtual instrumentation over conventional instruments - architecture of a virtual instrument and its relation to the operating system. LabVIEW: Basic arithmetic operations, Boolean operations | |
| Unit-2: G Programming | 7 hours |
| Software environment - palettes - data types and colour coding - editing, debugging and running a VI - data flow programming - modular programming - loops - local and global variables. LabVIEW: Sum of 'n' numbers using 'for' loop, 'While'loop. | |
| Unit-3: Programming Structure & Techniques | 7 hours |
| Programming Techniques: VIS and sub-VIS loops and charts, arrays, clusters and graphs, case and sequence structures, formula nodes, local and global variables, string and file I/O, Graphical | |

| | |
|---|---|
| programming in data flow, comparison with conventional programming. Arrays and clusters - sequence structures - plotting data - making decisions in a vi - strings and File I/O - semaphores - TCP/IP - shared variables - data publishing - state machines LabVIEW: Array maximum and minimum | |
| Unit-4: Hardware Overview & Common Instrument Interfaces | 7 hours |
| PC architecture: current trends - operating system requirement drivers - interface buses - PCI, PXI and USB buses - interface cards: specifications LabVIEW: Application using formula node; Current loop, RS.232C/RS.485, GPIB, System buses, interface buses: USB, PCMCIA, VXI, SCXI, PXI, etc., networking basics for office &.Industrial applications, Visa and lVI, image acquisition and processing. Motion control. ADC, DAC, DIO, DMM, waveform generator. | |
| Unit-5: Data Acquisition Basics | 7 hours |
| ADC, DAC, DIO, Counters & timers, PC Hardware structure, timing, interrupts, DMA, Software and Hardware Installation. GPIB/IEEE 488 concepts, and embedded system buses - PCI, EISA, CPCI, and USB & VXI. A; Classification of signals - analog and digital interfacing - DAQ hardware and software - configuring the hardware - ADC, DAC, Digital I/O, counters and timers - advanced triggering of audio and video signals - basic system components of a signal conditioning system. LabVIEW: Instrumentation of an amplifier to acquire an ECG signal using NI vision acquisition software | |
| Unit-6: Use of Analysis Tools | 5 hours |
| Fourier transforms, power spectrum correlation methods, windowing & filtering, Major equipments- Oscilloscope, Digital Multimeter, Pentium Computers, Application in Biomedical field. | |

Suggested Readings:

1. Kevin James, “PC Interfacing and Data Acquisition: Techniques for Measurement, Instrumentation and Control”, Newnes, 2000. Lab VIEW Basics I &II Manual, National Instruments, 2005. Barry E Paton, “Sensors, Transducers & LabVIEW”, Prentice Hall of India, New Delhi, 1999

2. Johnson G, Jennings R, “LabVIEW Graphical Programming”, Tata McGraw Hill, New York, 2006. Sanjay Gupta, Joseph John, “Virtual Instrumentation using LabVIEW”, Tata McGraw Hill, New Delhi, 2010.

| **Name of The Course** | **Advanced Biomedical Instrumentation** | | | |
|---|---|---|---|---|
| **Course Code** | **BMET 6005** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| L | T | P | C | |
| 3 | 0 | 0 | 3 | |

Course Objectives:
Students will understand about the Advanced Biomedical Instrumentation

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Physics of fiber optics |
| CO2 | Understand the Laser in biology |
| CO3 | Understand the Lasers in surgery |
| CO4 | Understand the biomedical Lasers |
| CO5 | Understand about the Digital Imaging and Communications in Medicine |
| CO6 | Analyze the |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Physics of fiber optics | 7 hours |
| Introductory physics of fiber optics, properties, Generation, transmission and detection of fiber optics - Fiber optics in diagnosis - Transmission of signals, light, and construction details of optical fiber, types of medical fiber optic scopes – Fiber optic sensors for temperature, pressure, liquid level, Doppler probe - Fiber optics endoscopy for various organs | |
| Unit-2: Laser in biology | 7 hours |
| Laser in biology: Optical properties of tissue, Pathology of laser reaction in skin, thermal effects, laser irradiation, Non thermal reactions of laser energy in tissue, effect of adjuvant. | |
| Unit-3: Lasers in surgery | 7 hours |
| Lasers in surgery: Surgical instrumentation of CO2, Ruby, Nd-YAG, He-Ne, Argon ion, Qswitched operations, continuous wave, Quasi – continuous, surgical applications of these lasers. Lasers in dermatology, lasers in ophthalmology, laser photocoagulations, laser in dentistry. | |
| Unit-4: biomedical Lasers | 7 hours |
| Speckle intereferometry, holography - Application Safety with biomedical Lasers. Basic principles of Multicolor lasers, plastic imaging multifibers, Intravascular pressure transducers and in vivo oximeters & Virtual reality assisted surgery planning | |
| Unit-5: Digital Imaging and Communications in Medicine | 7 hours |
| Digital Imaging and Communications in Medicine (DICOM) – data formats – services. Picture archiving and communication system (PACS) – architecture – Integration with Hospital information system (HIS) and Radiology Information System (RIS) – Digital Radiography | |
| Unit-6: Biodevices | 5 hours |
| ESWL - Smart pacemakers - Minimally invasive robotic surgery - Drug encapsulation - Gene Therapy – Molecular scans - Real time imaging of the Coronary Arteries – Nanomaterials - Smart textiles - Electroactive fabrics and wearable biomonitoring devices – the Bionic person – Nanomotors | |

Suggested Readings:

1. Ronald W. Waynant, Lasers In Medicine, Taylor & Francis Ltd CRC Press Inc, Hardcover – 2001 (UNITS I, II)

2. Abraham Katzir, Lasers and Optical Fibers in Medicine, Academic Press, Oct-1993 (UNIT III)

3. H. K. Huang, PACS: Basic Principles and Applications (Paperback), Wiley-Liss; 1 edition November, 1998. (UNIT IV)

4. Joseph D Bronzino, The Biomedical Engineering Handbook, CRC Press, Third Edition – Volume II & III (UNIT V)

# Elective-IV

| **Name of The Course** | **VLSI Design** | | | |
|---|---|---|---|---|
| **Course Code** | **BMET 6006** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| L | T | P | C | |
| 3 | 0 | 0 | 3 | |

Course Objectives:
Students will understand about the VLSI Design

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Introduction to IC Technology |
| CO2 | Understand the VHDL basics |
| CO3 | Understand the Component declarations |
| CO4 | Understand the Concurrent statements |
| CO5 | Understand about the VHDL synthesis |
| CO6 | Analyze the Design of Arithmetic Building Blocks and Subsystem |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Introduction to IC Technology | 7 hours |
| Introduction to IC Technology – MOS, PMOS, NMOS, CMOS & BiCMOS technologiesPass transistor, NMOS Inverter, Various pull ups, CMOS Inverter analysis and design-Gate realization using CMOS-Introduction to Reconfigurable Hardware – HDL basics. | |
| Unit-2: VHDL basics | 7 hours |
| VHDL basics - VHDL levels of abstraction - Abstraction and timing - The VHDL design flow - VHDL design entities - Entity declarations - Architectures - Using libraries and packages - Concurrent signal assignments - Signal assignments with delays | |
| Unit-3: Component declarations | 7 hours |
| Component declarations - Component instantiation - Named port mapping - Positional port mapping - Direct instantiation - Configuration specifications - Entity binding Port modes - VHDL processes - Processes sensitivity lists - Objects in VHDL - Constants, variables and signals - VHDL types - Scalar types - Arrays – Records - Custom types and subtypes | |
| Unit-4: Concurrent statements | 7 hours |
| Concurrent statements - Sequential statements - Conditional & selective signal assignments - The generate statement - Signal and variable assignments - For loops - Subprograms – Functions – Procedures - Differences between functions and procedures - Subprogram declarations – Packages - Package declaration - Package body. | |
| Unit-5: VHDL synthesis | 7 hours |
| VHDL synthesis - Modeling hardware in VHDL - VHDL models for multiplexers, Encoders, Decoders, Parity Generators – combinational circuit implementation - compilation and simulation of VHDL code, modeling a sequential machine, Test bench development. | |
| Unit-6: Design of Arithmetic Building Blocks and Subsystem | 5 hours |
| Arithmetic Building Blocks: Data Paths, Adders, Multipliers, Shifters, ALUs, power and speed tradeoffs, Case Study: Design as a tradeoff.Designing Memory and Array structures: Memory Architectures and Building Blocks, Memory Core, Memory Peripheral Circuitry. | |

Suggested Readings:

1. Chip Design for Submicron VLSI: CMOS Layout & Simulation, - John P. Uyemura, Thomson Learning.
2. Introduction to VLSI Circuits and Systems - John .P. Uyemura, JohnWiley, 2003.
3. Digital Integrated Circuits - John M. Rabaey, PHI, EEE, 1997.
4. Modern VLSI Design - Wayne Wolf, Pearson Education, 3rd Edition, 1997.

| | | | | | |
|---|---|---|---|---|---|
| **Name of The Course** | **Biotransport Process** | | | | |
| **Course Code** | **BMET 6007** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

Course Objectives:
Students will understand about the Biotransport Process

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Basic concepts of transport processes |
| CO2 | Understand the Heat transfer systems |
| CO3 | Understand the Mass transfer principles |
| CO4 | Understand the Mass transfer in artificial kidney devices |
| CO5 | Understand about the Compartmental models |
| CO6 | Analyze the Modeling of the body as compartment |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Basic concepts of transport processes | 7 hours |
| Basic concepts of transport processes. Relationship between flow and effort variables. Chemical balances, force balances, general flow balances, Kirchhoff's laws, Conservation of mass, conservation of energy, momentum balance | |
| Unit-2: Heat transfer systems | 7 hours |
| Heat transfer systems. Modes of heat transfer, conduction, convection and radiation. Heat production, heat loss to the environment, role of blood circulation in internal heat transfer, models for heat transfer within the body. | |
| Unit-3: Mass transfer principles | 7 hours |
| Mass transfer principles. Mass balance, molecular diffusion, Transport through cell membranes. Mass transfer in kidneys, models of nephron function, gas transport mechanisms in the lungs and blood. Modelling of oxygen and inert gas uptake in the lungs. | |
| Unit-4: Mass transfer in artificial kidney devices | 7 hours |
| Mass transfer in artificial kidney devices, modeling of patient-artificial kidney system. Comparison of natural and artificial lungs. Models for blood oxygenation, analysis of gas transport in membrane oxygenators. | |
| Unit-5: Compartmental models | 7 hours |
| Compartmental models. Approaches to pharmacokinetic modeling and drug delivery, one and two compartmental models. Physiological applications-intravenous injection, constant intravenous infusion, determination of regional blood flow volumes and blood flow rates. | |
| Unit-6: Modeling of the body as compartment | 5 hours |
| Modeling of the body as compartment; Source and stream; heat exchange between human body and its environment; mass transfer in membrane; heamodialysis as related to artificial kidney; Oxygen Transport in Biological Systems, extracorporeal devices, Pharmacokinetic Analysis. | |

Suggested Readings:

1. “Biomedical Engineering Principles, An Introduction to fluid , heat and mass transfer process”, Cooney D. O., Marcel Dekker Inc, (1976).
2. “Transport Phenomena is living systems- Biomedical Aspects of Momentum and Man Transport”, Lightfoot E. N., John Wiley (1974).
3 “Basic transport phenomena in biomedical engineering”, Fournier, Ronald L., Taylor & Francis, 1998.

# Semester VII

| **Name of The Course** | **BioMEMS and Biosensors** | | | |
|---|---|---|---|---|
| **Course Code** | **BMET 7001** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives:
Students will understand about the BioMEMS and Biosensors

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Introduction to BioMEMS |
| CO2 | Understand the Soft fabrication and polymers |
| CO3 | Understand the MEMS biosensors |
| CO4 | Understand the Microarrays |
| CO5 | Understand about the Biological sensors |
| CO6 | Analyze the Applications of biosensors |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Introduction to BioMEMS | 7 hours |
| Introduction to bio-MEMS. Materials for bio-MEMS. BioMEMS fabrication: bulk/surface micromachining, LIGA. | |
| Unit-2: Soft fabrication and polymers | 7 hours |
| Soft fabrication and polymers (soft-lithography, micromolding, micro- stereolithography, thick-film deposition, SAMs. Microfluidic principles. Microfluidic devices: microchannels, microvalves, micropumps, micro- needles, microreserviors, micro-reactors; | |
| Unit-3: MEMS biosensors | 7 hours |
| MEMS biosensors. Microactuators and micro drug delivery system. Micro total analysis system (μTAS), lab-on-a-chip. | |
| Unit-4: Microarrays | 7 hours |
| Microarrays: polymerase chain reactor (PCR), DNA chip, functional genomics, bioinformatics. BioMEMS for tissue engineering. Packaging, power, data and RF safety of bioMEMS | |
| Unit-5: Biological sensors | 7 hours |
| Chemoreceptors, Baroreceptors, Touch receptors; Biosensors; Working Principle and Types, - molecular recognition elements, transducing elements. | |

| Unit-6: Applications of biosensors | 5 hours |
|---|---|
| Enzyme-based biosensors, e.g., the blood glucose sensor; Array-based DNA "biochip" sensors with fluorescence detection; Applications of molecular recognition elements in nanosensing of different analytes; Application of various transducing elements as part of nanobiosensors | |

Suggested Readings:


1. Mauro Ferrari (editor), BioMEMS and Biomedical Nanotechnology: I: Prospectus, Biological and Biomedical Nanotechnology (A. Lee, L. Lee); II: Micro and Nano-Technologies for Genomics and Proteomics (M. Ozkan and M. Heller); III: Therapeutic Micro/Nanotechnology (T. Desai and S. Bhatia); IV: Biomolecular Sensing, Processing and Analysis (R. Bashid and S. Wereley), Springer, 1st edition, Nov. 30, 2006, ISBN: 0387255613
2. Gerald Urban, BioMEMS (Microsystems), Springer, 1st edition, May 5, 2006, ISBN: 0387287310.
3. Wanjun Wang, Steven A. Soper, Bio-MEMS: Technologies and Applications, CRC Press, 1st edition, Dec. 15, 2006, ISBN: 0849335329.
4. Ville Kaajakari, Practical MEMS: Design of microsystems, accelerometers, gyroscopes, RF MEMS, optical MEMS, and microfluidic systems, Small Gear Publishing, Mar. 17, 2009, ISBN: 0982299109.
5. Marc J. Madou, From MEMS to Bio-MEMS and Bio-NEMS: Manufacturing Techniques and Applications, CRC Press, 1st edition, Jun. 16, 2010, ISBN: 142005516X. Ellis Meng, Biomedical Microsystems, CRC Press, 1st edition, ISBN: 1420051229, Sept. 17, 2010.


| **Name of The Course** | **Artificial Intelligence & Pattern Recognition** | | | |
|---|---|---|---|---|
| **Course Code** | **BMET 7002** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives:
Students will understand about the Artificial Intelligence & Pattern Recognition in biomedical engineering applications

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Introduction to Artificial Intelligence |
| CO2 | Understand the Knowledge representation |
| CO3 | Understand the Pattern Recognition Concepts |
| CO4 | Understand the Linear discriminant functions |
| CO5 | Understand about the Supervised learning and clustering |
| CO6 | Analyze the |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| Unit-1: Introduction to Artificial Intelligence | 7 hours |
|---|---|
| Definition of Artificial Intelligence, History and Applications, Components of AI Structures and Strategies for state space search- Data driven and goal driven search , Depth First and Breadth First | |

| | |
|---|---|
| Search, DFS with Iterative Deepening ,Heuristic Search- Best First Search, A* Algorithm, Constraint Satisfaction. | |
| Unit-2: Knowledge representation | 7 hours |
| Knowledge representation - Propositional calculus, Predicate Calculus, Theorem proving by Resolution, Answer Extraction, AI Representational Schemes- Semantic Nets, Conceptual Dependency, Scripts, Frames | |
| Unit-3: Pattern Recognition Concepts | 7 hours |
| Introduction to statistical, syntactic and descriptive approaches, features and feature extraction, learning; Bayes Decision theory- introduction, continuous case, 2-categoryclassification, minimum error rate classification, classifiers, discriminant functions, and decision surfaces. Error probabilities and integrals, normal density, discriminant functions for normal density, Bayes Decision theory Discrete case | |
| Unit-4: Linear discriminant functions | 7 hours |
| Linear discriminant functions- linear discriminant functions and decision surfaces, generalized linear discriminant functions, 2-category linearly separable case, non-separable behavior, linear programming procedures | |
| Unit-5: Supervised learning and clustering | 7 hours |
| Supervised learning and clustering- Mixture densities and identifiably, Maximum likelihood estimates, application to normal mixtures, unsupervised Bayesian learning, data description and clustering, Hierarchical clustering, low dimensional representation of multidimensional map | |
| Unit-6: Applications of deep learnin | 5 hours |
| Applications of deep learning to electronic health records and medical imaging data; Applications of deep learning to predicting protein structure and pharmacogenomics | |

Suggested Readings:


1. Stuart Russell and Peter Norvig. 2009. Artificial Intelligence: A Modern Approach (3rd ed.). Prentice Hall Press, Upper Saddle River, NJ, USA.
2. Toby Segaran. 2007. Programming Collective Intelligence (First ed.). O'Reilly.
3. Tony J. Cleophas and Aeilko H. Zwinderman. 2015. Machine Learning in Medicine - a Complete Overview. Springer
4. Sunila Gollapudi, S. 2016. Practical Machine Learning. Packt Publishing Ltd.
5. Peter Harrington. 2012. Machine Learning in Action. Manning Publications Co., Greenwich, CT, USA.


| **Name of The Course** | **Modeling of Physiological System** | | | | |
|---|---|---|---|---|---|
| **Course Code** | **BMET 7003** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | L | T | P | C | |
| | 3 | 0 | 0 | 3 | |

Course Objectives:
Students will understand about the Modeling of Physiological System

Course Outcomes:
After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the Basic Concepts of Physiological System |
| CO2 | Understand the Equivalent circuit model |
| CO3 | Understand the Linear Model |
| CO4 | Understand the Modelling of Blood flow and Urine formation |
| CO5 | Understand about the Cardio-Pulmonary Modelling |
| CO6 | Analyze the Eye Movement Model |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Contents

| | |
|---|---|
| Unit-1: Basic Concepts of Physiological System | 7 hours |
| Basic Concepts of Physiological System: Introduction to physiological system and mathematical modelling of physiological system The technique of mathematical modeling, classification of models-black box & building block, characteristics of models. Purpose of physiological modeling and signal analysis, linearization of nonlinear models. Engineering system and physiological system, System variables & properties- Resistance, Compliance & their analogy. Time invariant and time varying systems for physiological modeling. | |
| Unit-2: Equivalent circuit model | 7 hours |
| Equivalent circuit model: Electromotive, resistive and capacitive properties of cell membrane, change in membrane potential with distance, voltage clamp experiment and Hodgkin and Huxley's model of action potential, the voltage dependent membrane constant and simulation of the model, model for strength-duration curve, model of the whole neuron | |
| Unit-3: Linear Model | 7 hours |
| Linear Model: Respiratory mechanics & muscle mechanics, Huxley model of isotonic muscle contraction, modeling of EMG, motor unit firing: amplitude measurement, motor unit & frequency analysis. | |
| Unit-4: Modelling of Blood flow and Urine formation | 7 hours |
| Modelling of Blood flow and Urine formation: Electrical analog of blood vessels, model of systematic blood flow, model of coronary circulation, transfer of solutes between physiological compartments by fluid flow, counter current model of urine formation, model of Henle's loop | |
| Unit-5: Cardio-Pulmonary Modelling | 7 hours |
| Cardio-Pulmonary Modelling: Cardiovascular system and pulmonary mechanics modelling and simulation, Model of Cardiovascular Variability, Model of Circadian Rhythms | |
| Unit-6: Eye Movement Model | 5 hours |
| Eye Movement Model: Types of Eye movement, Eye movement system and Wetheimer's saccade eye model. Robinson's Model, Oculomotor muscle model, Linear Reciprocal Innervations Oculomotor Model | |

Suggested Readings:

1. Endarle, Blanchard & Bronzino, Introduction to Biomedical Engg. , Academic press.
2. Suresh.R.Devasahayam, Signals & Systems in Biomedical Engineering, Kluwer Academic/ Plenum Publishers.
3. V.Z. Marmarelis, Advanced methods of physiological modeling, Plenum Press.
4. J. Candy, Signal Processing: The Model Based approach, Mc. Graw Hill.
5. L.Stark, Neurological Control System, Plenum Press.
6. R.B. Stein, Nerve and Muscle, Plenum Press.

| Name of The Course | Hospital and Healthcare Administration | | | | |
|---|---|---|---|---|---|
| Course Code | BMET 7004 | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 3 | 0 | 0 | 3 |

Course Objectives:
The students will be familiarized with to know about Indian healthcare system: The Indian healthcare sector is expanding rapidly, with an estimated market value of US$ 280 billion by 2020.
This course will provide strategic insights and business skills for those working across the worldwide health sector.

Course Outcomes
On completion of this course the students will be able to understand

| | |
|---|---|
| CO1 | Basic concepts of Health, Natural history of disease and role of hospitals to offer various levels of care |
| CO2 | Introduction to Hospital Management, Concepts of Healthcare industry, Department and organization structure of different types of hospitals |
| CO3 | Hospital's Department, Supportive and Ancillary service Departments |
| CO4 | Basics of Drug Management, Computerized Drug management system |
| CO5 | Procurement of Drugs, Procedure of drug indenting |
| CO6 | Analyze the Health Systems in India |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Content

| |
|---|
| Unit-1: Basic Concepts of Health 7 hours |
| Concept of health & disease and well-being, Prevention aspect of diseases, Dynamics of disease transmission, Changing pattern of diseases, Common pathological conditions, Basic concepts of interpretation of investigations reports |
| Unit-2: Introduction to Hospital Management 7 hours |
| Concepts of Healthcare industry and its ever-changing character, terminal planning, design and operation, Concept of hospitals, space required for separate functions, overview, design & planning of different types of hospitals, Problems and constraints in hospitals. |
| Unit-3: Deparmentation in Hospital 6 hours |
| Organization, Structure, Vertical and Horizontal, Clinical and Non- Clinical, Supportive and Ancillary service Departments, Department and organization structure of different types of hospitals. |
| Unit-4 : Basics of Drug Management 7 hours |
| Drug Management, Hospital Pharmacy License and Drug License, Narcotics drug storage, Pharmacy billings, Computerized Drug management system, Rational use of Drugs and Prescription Audits, Spurious Drugs, Banned Drugs |
| Unit-5: Procurement of Drugs 6 hours |
| Purchase of drugs and other consumable materials, Procedure of drug indenting, On time drug dispensing inventory control, Methods of ordering – two bin system (lead time, buffer stock, reorder level) cyclic system |
| Unit-6 Health Systems in India 7 hours |
| Health planning in India including various committees and National Health Policy and Health Goals set from time to time. Organised sector with reference to Centre, State, District and Block level structures and local bodies and Panchayati Raj Organisation and functions of community health centres and Primary Health Centres (PHCs). Health Manpower, Primary Health care and concept, Alternative systems of medicine, like Ayurveda, Homeopathy, etc. Holistic Approach Non-Governmental Organisations (NGOs) and Private Voluntary Organisations (PVOs). Unorganized Sector |

Suggested Readings:

1. Hospital Management: Principle, Theory and Practice by Amit Virmani
2. Hospital Management: An Evaluation – by A.K. Malhotra
3. Principles of Hospital Administration & Planning: B.M. Sakharkar (Jaypee)

| Name of The Course | Fundamentals of Clinical Research | | | |
|---|---|---|---|---|
| Course Code | BMET 7005 | | | |
| Prerequisite | | | | |
| Co-requisite | | | | |
| Anti-requisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives

1. Students will be exposed to Clinical Research and their requirements, Pharmaceutical Industry, Bioavailability and Bioequivalence Studies.

Course Outcomes

| | |
|---|---|
| CO1 | Historical Aspects of clinical research, clinical research terminologies |
| CO2 | Phases of Clinical Trial and Types of Clinical Trial including Virtual Clinical Trials |
| CO3 | Pharmaceutical Industry and concepts of Intellectual Property Rights |
| CO4 | Modules of International Conference on Hormonization (Quality, Safety, Efficacy and Miscellaneous) and E6 Overview |
| CO5 | Drug Regulation and Evidence based medicine |
| CO6 | Analysis of Evidence-based medicine |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Exam (MTE) | End Term Exam (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Content:

| |
|---|
| Unit I: Basic Introduction to Clinical Research 7 Hours |
| Overview, Opportunities & Career options in Clinical Research, Glossary of GCP. Historical Aspects of clinical research, Brief description of different phases, Stakeholders in clinical research, Need/Area for clinical research. |
| Unit-2 Phases and Types of Clinical Trials 7 Hours |
| Introduction to Clinical Trials – Phases of Clinical Trials, Types of Clinical Trials, Randomized/Non randomized Clinical Trial, Virtual-clinical trials, Drug discovery and development. |
| Unit-3 Pharmaceutical Industry & globalization 7 Hours |
| Overview of global and local players, Intellectual Property Rights: Introduction, Scope, Objectives and concepts of IPR, Tangible & Intangible property, scope & nature of patents, copyrights, trademark, Indian Patent Act 1970, practical aspects of patent filing. |
| Unit-4: ICH Introduction 7 Hours |
| ICH Introduction, Origin, Organization, Structure, Modules of ICH (Quality, Safety, Efficacy and Miscellaneous), E6 Overview |

| Unit-5: Introduction to Indian GCP and ICMR | 5 Hours |
|---|---|
| Indian- good clinical practice, Overview of ICMR | |
| Unit-6: Evidence-based medicine | |
| Need for evidence based approach in making decisions in family medicine; difference between evidence based medicine and evidence based health care; classification of evidence – information levels; 5 steps process for use of evidence oriented approach in family medicine | |

Suggested Reading


17. Indian GCP Guideline.
18. NDCT 2019
19. Design and Analysis of Clinical Trials: Concepts and Methodologies, 3rd Edition. SheinChung Chow, Jen-Pei Liu. Publisher: Wiley.
20. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Publisher: Wiley-Blackwell
21. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., Dupin-Spriet T., Simon P. Publisher: Karger


# Elective-V

| Name of The Course | Introduction to Bioinformatics | | | |
|---|---|---|---|---|
| Course Code | BMET 7006 | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| | L | T | P | C |
| | 3 | 0 | 0 | 3 |

Course Objectives: Students are able to understand the basic concept of bioinformatics.

Course Outcomes

| | |
|---|---|
| CO1 | Describe the Introduction of Computer Fundamentals |
| CO2 | It Interpret the Introduction of Bioinformatics and Biological Databases |
| CO3 | Demonstrate Sequence Alignments, Phylogeny and Phylogenetic trees |
| CO4 | Evaluate Genome organization and analysis |
| CO5 | EvaluateProtein Structure Predictions |
| CO6 | Analyze the Biomolecular Simulations |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Content:

| Unit-1 Introduction To Computer Fundamentals | 7 hours |
|---|---|
| RDBMS - Definition of relational database, Mode of data transfer (FTP, SFTP, SCP), advantage of encrypted data transfer. | |
| Unit-2 Introduction To Bioinformatics And Biological Databases | 7 hours |

| |
|---|
| Biological databases - nucleic acid, genome, protein sequence and structure, gene expression databases, Database of metabolic pathways, Mode of data storage - File formats - FASTA, Genbank and Uniprot, Data submission & retrieval from NCBI, EMBL, DDBJ, Uniprot, PDB. |
| Unit-3 Sequence Alignments, Phylogeny And Phylogenetic Trees 7 hours |
| Local and Global Sequence alignment, pairwise and multiple sequence alignment. Scoring an alignment, scoring matrices, PAM & BLOSUM series of matrices. Types of phylogenetic trees, Different approaches of phylogenetic tree construction -UPGMA, Neighbour joining, Maximum Parsomony, Maximum likelihood. |
| Unit-4 Genome Organization And Analysis 7 hours |
| Diversity of Genomes: Viral, prokaryotic & eukaryotic genomes; Genome, transcriptome, proteome, 2-D gel electrophoresis, Maldi Toff spectroscopy; Major features of completed genomes: *E.coli*, *S.cerevisiae*, *Arabidopsis*, and Human. |
| Unit-5 Protein Structure Predictions 7 hours |
| Hierarchy of protein structure - primary, secondary and tertiary structures, modelling; Structural Classes, Motifs, Folds and Domains; Protein structure prediction in presence and absence of structure template; Energy minimizations and evaluation by Ramachandran plot Protein structure and rational drug design. |
| Unit-6 Biomolecular Simulations 5 hours |
| Force field and energy landscape; Minimization and alogrithms; Molecular dynamics; Free energy calculations; Membrane simulations |

Suggested Readings:


1. Saxena Sanjay (2003) A First Course in Computers, Vikas Publishing House
2. Pradeep and Sinha Preeti (2007) Foundations of Computing, 4th ed., BPB Publications
3. Lesk M.A.(2008) Introduction to Bioinformatics . Oxford Publication, 3rd International Student Edition
4. Rastogi S.C., Mendiratta N. and Rastogi P. (2007) Bioinformatics: methods and applications, genomics, proteomics and drug discovery, 2nd ed. Prentice Hall India Publication
5. Primrose and Twyman (2003) Principles of Genome Analysis & Genomics. Blackwell


| **Name of The Course** | **Molecular Diagnostics & Therapeutics** | | | |
|---|---|---|---|---|
| **Course Code** | **BMET 7007** | | | |
| Prerequisite | | | | |
| Corequisite | | | | |
| Antirequisite | | | | |
| L | T | P | C | |
| 3 | 0 | 0 | 3 | |

Course Objectives:

Students will understand about the tools and techniques used in the molecular diagnosis & Therapeutics.

Course Outcomes:

After completion of this course work students able to

| | |
|---|---|
| CO1 | Understand the basic concepts of host pathogen interactions and Biomarkers |
| CO2 | Understand the biochemical based diagnosis. |
| CO3 | Understand the DNA based diagnosis |
| CO4 | Understand the protein based diagnosis |
| CO5 | Understand the Cellular therapy |
| CO6 | Understand about the Recombinant therapy & Immunotherapy |

Continuous Assessment Pattern

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|

| | | | |
|---|---|---|---|
| 20 | 30 | 50 | 100 |

Course Content:

| | |
|---|---|
| Unit-1: Host pathogen interactions and Biomarkers | 7 hours |
| Biomarkers- types and applications; Host pathogen interactions in disease process; Protective immune response in Bacterial, Viral and Parasitic diseases; Cancer; Inappropriate Immune response; Disease pathology and clinical spectrum; Clinical diagnosis of diseases; Molecular Genetics of the host and the pathogen | |
| Unit-2: Biochemical based diagnosis | 7 hours |
| Biochemical disorders; Molecular techniques for analysis of these disorders; Assays for the Diagnosis of inherited diseases; Antibody based diagnosis; Monoclonal antibodies as diagnostic reagents; Production of monoclonal antibodies with potential for diagnosis; Diagnosis of bacterial, viral and parasitic diseases by using; ELISA and Western blot. | |
| Unit-3: DNA based diagnosis | 7 hours |
| Aptamers; DNA sequencing and diagnosis; PCR and Array based techniques in diagnosis; Single nucleotide polymorphism and disease association; Two dimensional gene scanning. | |
| Unit-4: Protein based diagnosis | 5 hours |
| Protein Micro array; Present methods for diagnosis of Specific diseases like Tuberculosis, Malaria and AIDS; Ethics in Molecular Diagnosis | |
| Unit-5: Cellular therapy | 7 hours |
| Cellular therapy; Stem cells: definition, properties and potency of stem cells; Sources: embryonic and adult stem cells; Concept of tissue engineering; Role of scaffolds; Role of growth factors; Role of adult and embryonic stem cells; Clinical applications; Ethical issues | |
| Unit-6: Recombinant therapy & Immunotherapy | 7 hours |
| Recombinant therapy; Clinical applications of recombinant technology; Erythropoietin; Insulin analogs and its role in diabetes; Recombinant human growth hormone; Streptokinase and urokinase in thrombosis; Recombinant coagulation factors; Immunotherapy; Monoclonal antibodies and their role in cancer; Role of recombinant interferons; Immunostimulants; Immunosupressors in organ transplants; Role of cytokine therapy in cancers; Vaccines: types, recombinant vaccines and clinical applications | |

Suggested Readings:


13. Campbell, M.A and Heyer L.J., Discovering Genomics, Proteomics and Bioinformatics, 2nd Edition, CSHL Press, Pearson/Benzamin Cummings San Francisco, USA, 2007.
14. Andrew Read and Dian Donnai, New Clinical Genetics, Scion Publishing Ltd, Oxfordshire, UK, 2007.
15. James W Goding, Monoclonal antibodies: Principles and Practice, 3rd Edition, Academic Press, 1996.
16. Bernhard Palsson and Sangeeta N Bhatia, Tissue Engineering, 2nd Edition, Prentice Hall, 2004.
17. George Patrinos and Wilhelm Ansorage, Molecular Diagnostics, 1 st Edition, Academic Press, 2005.
18. Lela Buchingham and Maribeth L Flawsm, Molecular Diagnostics: Fundamentals, Methods and Clinical Applications, 1 st Edition, F A Davis Company, Philadelphia, USA, 2007.


| **Name of The Course** | **Major Project** | | | | |
|---|---|---|---|---|---|
| **Course Code** | **BMEP 8051** | | | | |
| Prerequisite | | | | | |
| Corequisite | | | | | |
| Antirequisite | | | | | |
| | | L | T | P | C |
| | | 0 | 0 | 24 | 12 |

**Course Objectives:**

Students will get exposure of Project work execution in the area of Biomedical Engineering.

**Course Outcomes**

On completion of this course the students will be able to

| | |
|---|---|
| CO1 | Formulate questions and to discover feasible solutions |
| CO2 | Demonstrate individual initiative or group responsibility |
| CO3 | Use resource materials to express ideas and talents |
| CO4 | Design and execute the project work |
| CO5 | Report the project work in terms of thesis |

**Continuous Assessment Pattern**

| Internal Assessment (IA) | Mid Term Test (MTE) | End Term Test (ETE) | Total Marks |
|---|---|---|---|
| **60** | **00** | **240** | **300** |

**Course Content**

**Unit-1: Biomedical Engineering Major Project**

Six components are required for project completion: 1.Self-Management component

5. Written component 3. Research component 4. Oral component 5. Technological component 6. Visual component

This project work is to make the student acquainted with the Patient/Healthcare sector/ industrial/Medical Diagnosis and Therapeutics. After completion of the project they will have to submit dissertation report

This project work or thesis presents a student's research results, describing the research with reference to relevant work done as part of the live project at a Hospital/Healthcare sector/Biomedical Companies with specific diseases, diagnosis and therapeutic or rehabilitation engineering. It will include a description of the methods of research considered, and those actually employed, and present the student's conclusions. The thesis is the student's own work and must be written by the student.

The Internal Layout of the project work or Thesis

The thesis is to be submitted in the following pattern,

- Title page;
- Declarations and Statements
- Author's declaration
- Acknowledgement
- Contents page;
- Table of contents
- List of tables
- List of figures
- Definitions or Abbreviations
- Summary (Abstract)
- Introduction
- Literature Review
- Materials and Methods
- Results & Discussion
- Conclusion and Future Prospectives
- List of references
- Index