



NETAJI SUBHAS UNIVERSITY

Estd. Under Jharkhand State Private University Act, 2018

Department of Biotechnology

B. Sc. Biotechnology Course Curriculum (with CO, PO Structure)

w.e.f. 2022

NETAJI SUBHAS UNIVERSITY

JAMSHEDPUR



B.SC BIOTECHNOLOGY

SYLLABUS

2022 ONWARDS

3091 Head
Department of Bio-Technology
Netaji Subhas University



Debnome
Dean Academics
Netaji Subhas University
Jamshedpur, Jharkhand



NETAJI SUBHAS UNIVERSITY
DEPARTMENT OF BIOTECHNOLOGY

Vision: Providing graduates equipped with excellent theoretical knowledge and practical skills and promoting scientific research and community service.

Mission

- To provide students a unique and multidisciplinary learning experience that will foster the young minds to develop as a researcher, entrepreneur etc.
- To enhance academic and industrial collaborative research initiatives for the development of biotechnological, food and therapeutic products.
- To emphasize and equip the students towards innovative industrial and research updates.
- To serve the society with utmost commitment, integrity, enthusiasm and dedication.

Programme Outcome: POs

PO-1	Understand and inculcate the ability to apply, update, extend and to developed knowledge through flexible, research intensive program designed to meet the current demand of academia and industry.
PO-2:	Demonstrate professional integrity and ethical attitude with awareness of global and national competencies and think about the social entailment of their work, especially its impact on safety, health and environment for sustainable development.
PO-3	Apply the acquired practical skills and broad biotechnological training in product, process and inculcate leadership qualities for innovative entrepreneurship to meet the societal demands.
PO-4	Ability to design and conduct experiments, as well as to analyze and interpret scientific data.
PO-5	Awareness of contemporary issues that can be mitigated or supported through life science knowhow and biotechnology skills.
PO-6	Equipped with laboratory skills in biotechnology.
PO-7	Ability to integrate technologies through an inter-disciplinary learning habit.
PO-8	Demonstrate an independent thinking ability. Ability to communicate effectively.

Programme Specific Outcome-PSOs

PSO-1: To teach the application of biotechnology skills in core and related fields, such as molecular and microbiology, immunology and genetic engineering, fermentation and bioprocess, enzyme and food technology, and bioinformatics.

PSO-2: To foster students' scientific curiosity and give them the ideas and research methodologies they need for a future in biotechnology.

PSO-3: To meet industry and academic demands by providing students with comprehensive, practically oriented knowledge in a variety of biotechnology thrust areas.

PSO4: To demonstrate proficiency in applying technical concepts to biological systems by demonstrating a working knowledge of advanced biological sciences.

PSO5: In order to solve biotechnological challenges, one must be adopting sophisticated biological concepts and methods.

PSO6: Researching complicated issues in biotechnology and related fields by designing, executing, analyzing, and interpreting data.



Netaji Subhas University

Syllabus for 3-Years B.Sc. (Honors). Biotechnology

SEMESTER I

S.No	Code	Subject	Credit	Examination		Marks Detail	
				External Exam	Internal Exam	Practical	Total
1	BSC101	Biotechnology-I	4	40	10	-	50
2	BSC102	Pharma Chemistry-I OR Computer Science-I	4	40	10	-	50
3	BSC103	Animal Physiology	4	40	10	-	50
4	BSC101P	Biotechnology-I Practical	2	-	-	50	50
5	BSC102P	Pharma Chemistry I OR Computer science-I Practical	2	-	-	50	50
6	BSC103P	Animal Physiology Practical	2	-	-	50	50
7	BSC104	English Language-I	4	40	10	-	50
		Total	22				350



Netaji Subhas University

Syllabus for 3-Years B.Sc. (Honours). Biotechnology

Semester-II

S.No	Code	Subject	Credit	Examination		Marks Detail	
				External Exam	Internal Exam	Practical	Total
1	BSC201	Biotechnology-II	4	40	10	-	50
2	BSC202	Pharma Chemistry-II OR Computer Science-II	4	40	10	-	50
3	BSC203	Plant Physiology	4	40	10	-	50
4	BSC201P	Biotechnology II Practical	2	-	-	50	50
5	BSC202P	Pharma Chemistry-II OR Computer Science-II Practical	2	-	-	50	50
6	BSC203P	Plant Physiology Practical	2	-	-	50	50
	BSC204	English Language-II	4	40	10	-	50
		Total	22				350



Netaji Subhas University

Syllabus for 3-Years B.Sc. (Honours). Biotechnology

SEMESTER III

S.No.	Code	Subject	Credit	Examination Marks Detail			
				External Exam	Internal Exam	Practical	Total
1	BSC301	Biotechnology-III	4	40	10		50
2	BSC302	Pharma Chemistry-III OR Computer Science-III	4	40	10		50
3	BSC303	Environmental Studies-I	4	40	10	-	50
4	BSC304	Entrepreneurship Development-I	4	40	10	-	50
5	BSC301P	Biotechnology- III Practical	2	-	-	50	50
6	BSC302P	Pharma Chemistry-III OR Computer Science-III Practical	2	-	-	50	50
		Total	20				300



NetajiSubhasUniversity

Syllabusfor3-YearsB.Sc.(Honours). Biotechnology

SEMESTERIV

S.No	Code	Subject	Credit	Examination Marks Detail			
				External Exam	Internal Exam	Practical	Total
1	BSC401	Biotechnology-IV	4	40	10		50
2	BSC402	Pharma Chemistry-IV OR Computer Science-IV	4	40	10		50
3	BSC403	Environmental Studies-II	4	40	10	-	50
4	BSC404	Entrepreneurship Development-II	4	40	10	-	50
5	BSC401P	Biotechnology- IV Practical	2	-	-	50	50
6	BSC402P	Pharma Chemistry-IV OR Computer Science-IV Practical	2	-	-	50	50
		Total	20				300



Netaji Subhas University

Syllabus for 3-Years B.Sc. (Honours). Biotechnology

SEMESTER V

S.No.	Code	Subject	Credit	Examination Marks Detail			
				External Exam	Internal Exam	Practical	Total
1	BSC501	Biotechnology-V	4	40	10	-	50
2	BSC502	Pharma Chemistry-V OR Computer Science-V	4	40	10	-	50
3	BSC503	Biotechnology Forensics Science	4	40	10	-	50
4	BSC504	Intellectual property rights (IPR)	4	40	10	-	50
5	BSC501P	Biotechnology-V Practical	2			50	50
6	BSC502P	Pharma Chemistry-V OR Computer Science V Practical	2			50	50
		Total	20				300



Netaji Subhas University

Syllabus for 3-Years B.Sc. (Honors). Biotechnology

Semester-VI

S.No.	Code	Subject	Credit	Examination Marks Detail			
				External Exam	Internal Exam	Practical	Total
1	BSC601	Biotechnology-VI	4	40	10	-	50
2	BSC602	Pharma Chemistry-VI OR Computer Science-VI	4	40	10	-	50
3	BSC603	Project (Biotechnology)	10	-	-	-	100
4	BSC604	Project(Pharma Chemistry) OR Project(Computer Science)	10	-	-	-	100
5	BSC601P	Biotechnology-VI Practical	2	-	-	50	50
6	BSC602P	Pharma Chemistry-VI OR Computer Science-VI Practical	2	-	-	50	50
		Total	32				400

BSC-101–BIOTECHNOLOGY-I

CELLSTRUCTURE&BIOLOGY

MAX.MARKS:40+10

No. of Lectures per Week:02 Hours

TOTALLECTURES: 32

The Question Paper will contain questions equally distributed in all Units. The Internal Choice will be given in all Questions.

The course objectives of Cell Biology

CO1. Understanding Cell Structure & Function

- Learn about prokaryotic and eukaryotic cells, their organelles, and their specific functions.

CO2. Molecular Composition of Cells

- Study the biomolecules (proteins, lipids, carbohydrates, and nucleic acids) that make up the cell and their roles.

CO3. Cellular Processes & Metabolism

- Explore cell signaling, membrane transport, energy production (cellular respiration, photosynthesis), and enzyme functions.

CO4. Genetic and Molecular Basis of Life

- Understand DNA replication, transcription, translation, and gene expression regulation.

CO5. Cell Cycle & Division

- Learn about mitosis, meiosis, and the mechanisms that regulate cell proliferation and apoptosis.

Unit-I

Cell Structure & Theory, Structure of prokaryotic cell, Eubacteria and Archaeobacteria. Size, shape and arrangement of bacterial cells. Gram's positive and Gram's negative cells.

Structure of Eukaryotic cell, plant cells, animal cells. Difference between prokaryotic and eukaryotic cells.

Unit-II

Structure and function of bacterial cell — flagella, pill, Cell wall, cytoplasmic membrane, nuclear region, mesosomes, ribosomes, vacuoles.

Structure and function of eukaryotic cell — Cell wall, cell membrane, mitochondria, chloroplast, endoplasmic reticulum, Golgi bodies, nucleus, cytoskeleton, microbodies, Centriole, Lysosome.

Unit-III

Cell cycle and cell division-mitosis, meiosis .Anomalies in cell division and associated diseases. Cell synchrony, Cell-cell interactions.

Unit-IV

Transport Process: Cell Membrane: Models of membrane structure, Membrane proteins and their properties, Membrane carbohydrates and their roles .Transport across membranes — active and passive diffusion, mechanisms.

Unit-V

Introduction to Necrosis, Senescence, Apoptosis—Programmed cell death .Mechanism of Apoptosis ,Intrinsic &Extrinsic pathways of cell death, Apoptosis in relation to Cancer, Oncogenes — Types of cancer.

BOOKS:

1. Molecular Biology of the cell, 2002: Albert's et al
2. The cell: A molecular approach: J.M. Cooper
3. Cell biology: P.S. Verma and V.K. Agarwal
4. Cell and Molecular Biology: P.K. Gupta
5. Experiments in Biotechnology: Nigrojkar and Nigrojkar
6. A practical book of Molecular Biology and Immunology: 2017: P .K. Singh *et al*

BIOTECHNOLOGY-IPRACTICALS

MAX.MARKS:50

No. of Laboratory per Week: 06 Hours

1. To study the plant cell structure using various plant materials.
2. To study microbial cell by Monochrome stains and Gram staining.
3. To prepare and study the different stages of mitosis and meiosis.
4. Prepare slide for study of stomata.
5. Study of permanent slides like cell division, prokaryotic and eukaryotic cells, Muscles and Nerve cells, T.S. of stomata.
6. To study the animal cell structure using cheek cells.
7. Histochemical localization of flagellin.
8. Viable cell counting using haematocytometer.
9. Measurement of cell by light microscope:-Calibration of ocular micrometer, finding out average cell size
10. Separation of cell types from blood by TLC/differential counting.
11. Methods of cell lysis: rupture osmotic/chemical/enzymatic.

Course Outcomes of Cell Biology

Upon successful completion of the **Cell Biology** course, students will be able to:

CO1. Explain Cell Structure and Function

- Identify and describe the differences between prokaryotic and eukaryotic cells, their organelles, and their specific functions.

CO2. Understand Molecular Composition of Cells

- Demonstrate knowledge of biomolecules (proteins, lipids, carbohydrates, and nucleic acids) and their roles in cellular activities.

CO3. Analyze Cellular Processes and Metabolism

- Explain membrane transport mechanisms, enzyme functions, energy metabolism (cellular respiration, photosynthesis), and homeostasis.

CO4. Comprehend Genetic and Molecular Basis of Life

- Describe DNA replication, gene expression, transcription, and translation, and understand their regulation.

CO5. Understand Cell Cycle and Division

- Explain the stages of the cell cycle, mitosis, meiosis, and apoptosis, and their significance in growth and development.

BSC-102–ANIMALPHYSIOLOGY

MAX.MARKS:40+10

No .of Lectures per Week: 02Hours

The Question Paper will contain questions equally distributed in all Units. The Internal Choice will be given in all Questions.

Course Objectives of Animal Physiology

The **Animal Physiology** course aims to provide students with a fundamental understanding of the physiological processes that regulate and maintain life in animals. The key objectives include:

CO1. Understand the Fundamental Principles of Animal Physiology

- Learn the basic concepts of homeostasis, biological regulation, and physiological adaptations in different animal species.

CO2. Explore the Structure and Function of Organ Systems

- Study the anatomy and physiology of major organ systems, including circulatory, respiratory, digestive, excretory, nervous, endocrine, and reproductive systems.

CO3. Analyze Neurophysiology and Endocrine Regulation

- Understand the functions of the nervous system, signal transmission, and hormonal control mechanisms in animals.

CO4. Comprehend Energy Metabolism and Nutrient Utilization

- Learn how animals generate and utilize energy, including metabolic pathways, thermoregulation, and nutrient absorption.

CO5. Examine Circulatory and Respiratory Systems

- Study the mechanisms of oxygen transport, blood circulation, gas exchange, and adaptations to different environmental conditions.

<u>Unit-I</u>	<u>12 Lectures</u>
Digestion Digestion: Definition and types (extra and intracellular digestion); Digestion, absorption and assimilation of Carbohydrates.	
<u>Unit-II</u>	<u>12 Lectures</u>
Respiration Definition of Respiration and Respiratory mechanisms – External, Internal and cellular. Respiratory Pigments; Transport of oxygen, Oxygen dissociation curves. Bohr's effect	
<u>Unit-III</u>	<u>14 Lectures</u>
Circulation: Types of circulation - Open and Closed circulation; Blood and its types and function	
<u>Unit-IV</u>	<u>12 Lectures</u>
Excretion Definition; Classification (Ammonotelic, Uricotelic, Ureotelic), Structure and function of Nephron	
<u>Unit-V</u>	<u>14 Lectures</u>
Endocrine System Endocrine glands - Structure, secretions and functions of Pituitary, Thyroid, Parathyroid, Adrenal glands and Pancreas	

BOOKS:

1. Hughes, G.M. Comparative Physiology of vertebrate respiration(1963)Cambridge.
2. Guyton and Hall (2001) text book of medical physiology.
3. Schmidt –Neilson ,K (2002) Animal physiology ,Adaptation and environment
4. Cell and Molecular Biology: P.K. Gupta
5. Websteir ,R. Neurotransmitters , drugs and brain function.
6. A practical book of Molecular Biology and Immunology; 2017: P.K. Singh *et al*

BIOTECHNOLOGY-IPRACTICALS

MAX.MARKS: 50

No. of Laboratory per Week: 06 Hours

1. Qualitative tests for identification of carbohydrates.
2. Qualitative tests for identification of proteins
3. Qualitative tests for identification of lipids
4. Qualitative tests for identification of ammonia.
5. Qualitative tests for identification of urea
6. Estimation of Haemoglobin by Sahlis method.
7. Estimation of total protein by Lowry's method
8. Blood Test

Course Outcomes of Animal Physiology

Upon successful completion of the **Animal Physiology** course, students will be able to:

CO1. Explain the Principles of Animal Physiology

- Describe the fundamental physiological processes that regulate homeostasis and maintain life functions in animals.

CO2. Understand Organ System Functions

- Identify and explain the structure and function of major organ systems, including circulatory, respiratory, digestive, excretory, nervous, endocrine, and reproductive systems.

CO3. Analyze Neurophysiological and Endocrine Mechanisms

- Explain how the nervous and endocrine systems coordinate body functions through neural signaling and hormonal regulation.

CO4. Describe Energy Metabolism and Nutrient Utilization

- Understand metabolic pathways, thermoregulation, and the physiological mechanisms of digestion and absorption.

CO5. Explain Circulatory and Respiratory Processes

- Analyze the transport of gases, blood circulation, and adaptations of the cardiovascular and respiratory systems to different environments.

CO6. Understand Muscle Physiology and Movement

- Describe the mechanisms of muscle contraction, biomechanics, and the role of the skeletal and muscular systems in locomotion.

BSC- 201 – BIOTECHNOLOGY- II

MICROBIOLOGY

MAX.MARKS:40+10

TOTALLECTURES:32

The Question Paper will contain questions equally distributed in all Units. The Internal Choice will be given in all Questions.

Course Objectives of Microbiology

The **Microbiology** course aims to provide students with a fundamental understanding of microorganisms, their structure, function, and roles in health, industry, and the environment. The key objectives include:

CO1. Understand the Fundamentals of Microbiology

- Learn the history, scope, and importance of microbiology in various fields.

CO2. Classify and Describe Microorganisms

- Study the characteristics, classification, and diversity of bacteria, viruses, fungi, protozoa, and algae.

CO3. Explain Microbial Structure and Function

- Understand the cellular organization, physiology, and reproduction of microorganisms.

CO4. Understand Microbial Growth and Control

- Learn about microbial growth conditions, culture techniques, and methods for controlling microbial populations.

CO5. Explore Microbial Metabolism and Genetics

- Study metabolic pathways, enzyme functions, microbial genetics, and gene expression regulation.

Unit-I
Introduction of Microbiology History, Applications & Status of Microbiology in India. Classification of Microorganisms-General Features, systems of Classification.
Unit-II
Structure and Diversity of Bacteria & Virus, Microbes in extreme environment. Nutritional requirement of microbes. Bacteriology: Morphology and ultra-structure of bacteria and its morphological types, Archaeobacteria.
Unit-III
Various methods of staining: Simple, Gram staining, Endospore staining and capsule staining.
Unit-IV
Microbial growth — mathematical expression of growth, growth curve, factors affecting growth. Quantification of microbial growth. Control of microorganisms- physical & chemical, Evaluation of chemical disinfectants-tube dilution test, agar diffusion test and phenol- coefficient.
Unit-V
Microbial Nutrition and metabolism- Microbial Metabolism- Concept of Anabolism & catabolism processes. Nitrogen Fixation- Types and mechanisms, Microbial disease in plants & Animals (Only General concept). Fermentation Process —Fermenter & its microbes of industrial importance.

BOOKS:

1. Textbook of Microbiology: Prescott
2. Textbook of Microbiology: Pelczar, Pelczar and Chan
3. Textbook of Microbiology: RC Dubey and DK Maheshwari
4. General Microbiology Vol. I and II : Powar and Dhagniwala
5. Experiments in Biotechnology: Nighojkar and Nighojkar
6. Experiments in microbiology, plant pathology and Biotechnology: KR Aneja
7. Microbiology; A practical approach: Bhavesh Patel

BIOTECHNOLOGY-IIPRACTICALS

BIOTECHNOLOGY-IIPRACTICALS

MAX. MARKS:50

No. of Laboratory per Week: 06 Hours

1. Aseptic techniques, cleaning of glassware, Preparation of cotton plugging and sterilization.
2. Isolation of Microbes from Air, Water and Soil.
3. Dilution and plating by pour plate, Spread Plate Methods.
4. Staining Method—Gram Staining, Endospore Staining, Fungal Staining. Algal staining.
5. Identification of Bacteria based on staining, shape and size.
6. Antibiotic Sensitivity of Microbes by the Use of Antibiotic Discs.
7. Isolation and Identification of aquatic Fungi from Local water body.
8. Isolation and Characterization of green algae from Natural habitats.
9. Measurement of water and soil, pH.

Course Outcomes of Microbiology

Upon successful completion of the **Microbiology** course, students will be able to:

CO1. Explain the Fundamentals of Microbiology

- Describe the history, scope, and significance of microbiology in various fields, including medicine, industry, and environmental sciences.

CO2. Classify and Characterize Microorganisms

- Identify and differentiate between major microbial groups such as bacteria, viruses, fungi, protozoa, and algae based on their structure, function, and classification.

CO3. Understand Microbial Structure and Physiology

- Explain the cellular organization, morphology, growth requirements, and metabolic pathways of different microorganisms.

CO4. Demonstrate Knowledge of Microbial Growth and Control

- Apply knowledge of microbial growth kinetics, culture methods, sterilization, and disinfection techniques in laboratory and industrial settings.

CO5. Analyze Microbial Metabolism and Genetics

- Understand microbial enzymatic processes, metabolic pathways, gene expression, mutations, and genetic engineering applications.

BSC-202–PLANT PHYSIOLOGY

MAX.MARKS:40+10

No. of Lectures per Week: 02 Hours

The Question Paper will contain questions equally distributed in all Units. The Internal Choice will be given in all Questions.

Course Objectives of Plant Physiology

The **Plant Physiology** course aims to provide students with a comprehensive understanding of the functional and physiological processes in plants. The key objectives include:

CO1. Understand the Fundamental Concepts of Plant Physiology

- Learn the basic principles of plant structure, function, and growth processes.

CO2. Explore Plant Water Relations and Mineral Nutrition

- Study the mechanisms of water uptake, transport, transpiration, and the role of essential nutrients in plant growth and metabolism.

CO3. Analyze Photosynthesis and Respiration

- Understand the biochemical pathways of photosynthesis, respiration, and their significance in energy production and plant metabolism.

CO4. Examine Plant Growth and Development

- Study plant hormones, growth regulators, photoperiodism, seed germination, and flowering mechanisms.

CO5. Understand Transport Mechanisms in Plants

- Learn about phloem and xylem transport, translocation of nutrients, and source-sink relationships.

CO6. Study Stress Physiology and Adaptations

- Analyze plant responses to abiotic (drought, salinity, temperature) and biotic (pathogens, herbivores) stresses.

Unit-I	14 Lectures
Plant water relations , Diffusion, Osmosis, Water transport mechanisms, Transpiration and Stomatal physiology.	
Unit-II	12 Lectures
Minerals Nutrition in plants: types and function and deficiency disease.	
Unit-III	14 Lectures
Photosynthesis and General concept of photosynthesis, photosynthesis pigment, C2, Calvin cycle, C4 cycle and CAM pathway.	
Unit-IV	12 Lectures
Respiration: Photo oxidation of water, glycolysis, TCA cycle and ATP synthesis.	
Unit-V	12 Lectures
Plant growth regulators: Definition, Types (Auxins, Cytokinins, Gibberellin's, Ethylene & ABA) and Application.	

BOOKS:

1. Textbook of plant pathology Agrios, Academic Press London.
2. Plant physiology, Delvin, Yan Nostrand Reinhold comp. New York.
3. Textbook of various adaptation of plants ,Jones A.D And willbins.
4. Lyndon ,R.F 1990 Plant development, The cellular basis
5. Tayal M.S 1996 Plant anatomy. Rastogi publication, Meerut.

BSC-301–BIOTECHNOLOGY-III

BIOPHYSICS AND BIOCHEMISTRY

MAX.MARKS:40+10

No.of Lectures per Week: 02 Hours

The Question Paper will contain questions equally distributed in all Units. The Internal Choice will be given in all Questions.

Course Objectives of Biophysics and Biochemistry

The **Biophysics and Biochemistry** course aims to provide students with a fundamental understanding of the physical and chemical principles governing biological systems. The key objectives include:

Biophysics Objectives:

CO1. Understand the Physical Basis of Biological Processes

- Learn how principles of physics, such as thermodynamics, fluid mechanics, and electromagnetism, apply to biological systems.

CO2. Explore Biomolecular Interactions

- Study the physical forces governing protein folding, enzyme activity, and molecular recognition.

CO3. Analyze Biomechanics and Bioenergetics

- Understand the physical principles behind muscle contraction, cellular motility, and energy transformations in biological systems.

Biochemistry Objectives:

CO1.Understand the Structure and Function of Biomolecules

- Learn about proteins, nucleic acids, carbohydrates, and lipids and their role in cellular processes.

CO2. Explore Enzyme Kinetics and Metabolism

- Study enzyme mechanisms, metabolic pathways, and energy production in biological systems.

<u>Unit-I</u>	<u>12 Lectures</u>
Thermodynamics: Thermodynamic System, Equilibrium, Thermodynamic laws and their applications. Different types of processes, Thermodynamic variables and Entropy .	
<u>Unit-II</u>	<u>12 Lectures</u>
General Biophysical methods: Measurement of pH, Radioactive labeling & counting, Autoradiography. Diffusion, Sedimentation, Osmosis.	
<u>Unit-III</u>	<u>14 Lectures</u>
Fundamentals of Biochemistry: Biochemistry as molecular logic of living beings.. Chemical elements, structure of atoms, molecules and chemical bonds. Ionic, covalent, coordinate and hydrogen bonds. Structure, function and properties of water, Water as universal solvent, Acids, bases and salts, pH and buffers.	
<u>Unit-IV</u>	<u>12 Lectures</u>
Biomolecules: Introduction and occurrence, classification, properties, importance of carbohydrate, lipids, proteins, amino acids and nucleic acids and various types of RNA's.	
<u>Unit-V</u>	<u>14 Lectures</u>
Enzymes: Structure, classification and function -Active site. energy of activation, transition state hypothesis, lock and key hypothesis, induced fit hypothesis. Concept of Km- Michaelis Menten equation. Various types of enzyme inhibition. Introduction to Allosteric Enzymes. Definition of holoenzyme, Apo enzyme. Coenzyme, cofactor, prosthetic group and their examples. Concept of ribozyme.	

BOOKS:

1. Principles of Biochemistry Lehninger , Nelson & Cox.
2. Biochemistry ,Voet & Voet
3. Biochemistry ,Berg & Stryer
4. Text book of Biochemistry , S. P. Singh
5. Molecular Biology of the Cell , Bruce Alberd
6. Text book of Biochemistry , U . Satyanarayana
7. Experiments in Biotechnology: Nighojkar and Nighojkar

BIOTECHNOLOGY-III PRACTICALS

MAX. MARKS:50

No. of Laboratory per Week: 06 Hours

1. Principles and working knowledge of instruments like Colorimeter, pH meter, Centrifuge, Spectrophotometer, Microscope etc.
2. Qualitative analysis of Carbohydrates, Proteins and Lipids.
3. Quantitative estimation of Protein by Folin-Lowry method.
4. Quantitative estimation of sugar by Nelson Smogyi's method.
5. Determination of enzyme activity by amylase.
6. Study the effect of pH on enzyme activity.
7. Study the effect of temperature on enzyme activity.
8. Separation of amino acids by TLC
9. Separation of leaf pigments by Paper chromatography.
10. Estimation of hemoglobin.
11. RBC counting by haematocytometer.
12. WBC counting by Differential/ or total cell count.
13. Measurement of bleeding and clotting time.

Course Outcomes of Biophysics and Biochemistry

Upon successful completion of the **Biophysics and Biochemistry** course, students will be able to:

Biophysics Outcomes:

CO1. Understand the Physical Principles Governing Biological Systems

- Explain the application of physics concepts (thermodynamics, fluid dynamics, and electromagnetism) in biological processes.

CO2. Analyze Biomolecular Structures and Interactions

- Understand the principles of molecular interactions, including protein folding, enzyme kinetics, and ligand binding.

CO3. Explain Biomechanics and Bioenergetics

- Describe the physical forces involved in muscle contraction, cell motility, and energy transformation in biological systems.

Biochemistry Outcomes:

CO1. Explain Biomolecular Structure and Function

- Describe the chemical properties, structure, and biological roles of proteins, nucleic acids, carbohydrates, and lipids.

CO2. Understand Enzyme Mechanisms and Metabolism

- Explain enzyme kinetics, catalytic mechanisms, and metabolic pathways, including glycolysis, TCA cycle, and oxidative phosphorylation.

BSC-302–Environmental Studies-I

MAX.MARKS:50

No.of Lectures per Week: 02 Hours

The Question Paper will contain questions equally distributed in all Units. The Internal Choice will be given in all Questions.

Course Objectives of Environmental Science

The **Environmental Science** course aims to provide students with a comprehensive understanding of the environment, ecological processes, and human impact on natural systems. The key objectives include:

CO1. Understand the Fundamentals of Environmental Science

- Learn the basic principles, scope, and importance of environmental science in sustainability and conservation.

CO2. Explore Ecosystem Structure and Function

- Study ecological interactions, biodiversity, food chains, and energy flow in ecosystems.

CO3. Analyze Natural Resources and Their Management

- Understand the use, conservation, and sustainable management of air, water, soil, forests, and minerals.

CO4. Examine Environmental Pollution and Its Impact

- Study the causes, effects, and control measures for air, water, soil, and noise pollution.

CO5. Understand Climate Change and Global Environmental Issues

- Learn about greenhouse gases, global warming, ozone depletion, and strategies for climate change mitigation.

<u>Unit-I</u>	<u>12 Lectures</u>
Multidisciplinary nature of environmental studies Definition, scope and importance.	
<u>Unit-II</u>	<u>12 Lectures</u>
Natural Resources: Renewable and non-renewable resources, Natural resources and associated problems. a) Forest resources, b) Water resources, c) Mineral resources, d) Food resources, e) Energy resources f) Land resources.	
<u>Unit-III</u>	<u>14 Lectures</u>
Ecosystems: Concept of an ecosystem, Structure and function of an ecosystem, Producers, consumers and decomposers, Energy flow in the ecosystem.	
<u>Unit-IV</u>	<u>12 Lectures</u>
Food chains, food webs and ecological pyramids. Characteristic features and function of the following ecosystem: a. Forest ecosystem , b. Grassland ecosystem c. Desert ecosystem d. Aquatic ecosystems	
<u>Unit-V</u>	<u>14 Lectures</u>
Biodiversity: - Introduction- definition, genetic, species and ecosystem. Importance of Biodiversity. Biogeographical classification of India. India as a mega-diversity nation. Hot-spots of biodiversity. Threats to biodiversity, Endangered and endemic species of India. Conservation of biodiversity: In-situ and Ex-situ conservation of biodiversity	

BSC-303–ENTREPRENEURSHIPDEVELOPMENT-I

MAX.MARKS:50

No.of Lectures per Week: 02 Hours

The Question Paper will contain questions equally distributed in all Units. The Internal Choice will be given in all Questions.

Course Objectives of Entrepreneurship

The **Entrepreneurship** course aims to equip students with the knowledge, skills, and mindset required to start, manage, and grow a successful business. The key objectives include:

CO1. Understand the Fundamentals of Entrepreneurship

- Learn the definition, scope, and importance of entrepreneurship in economic development.

CO2. Explore Entrepreneurial Mindset and Characteristics

- Develop creativity, innovation, risk-taking ability, and problem-solving skills essential for entrepreneurs.

CO3. Identify Business Opportunities and Market Research

- Learn how to analyze market trends, identify business opportunities, and conduct feasibility studies.

CO4. Understand Business Planning and Strategy

- Develop a business model, draft a business plan, and formulate strategies for business success.

CO5. Learn About Funding and Financial Management

- Understand sources of funding, financial planning, budgeting, and resource management for startups.

CO6. Explore Legal and Ethical Aspects of Entrepreneurship

- Gain knowledge of business laws, taxation, intellectual property rights, and ethical business practices.

<u>08 Lectures</u>
Entrepreneurship Development — Concept and importance , Function of Enterprisar , Goal determination - Problems Challenges and solutions. Project Proposal — need and Objects —Nature of organization, Production Management, Financial Management , Marketing Management , Consumer Management . Role of regulatory Institutions Role of development organizations, self-employment oriented schemes. Major Motives Influencing an Entrepreneur – Achievement Motivation Training, Self-Rating, Business Games.

BSC-401–BIOTECHNOLOGY-IV

BIOINSTRUMENTATION, BIOSTATISTICS AND BIOINFORMATICS

MAX.MARKS:40+10

No .of Lectures per Week: 02 Hours

The Question Paper will contain questions equally distributed in all Units. The Internal Choice will be given in all Questions.

Course Objectives of Biostatistics and Bioinformatics

The **Biostatistics and Bioinformatics** course aims to provide students with a fundamental understanding of statistical methods and computational tools used in biological and biomedical research. The key objectives include:

Biostatistics Objectives:

CO1. Understand the Basics of Biostatistics

- Learn statistical concepts, data types, and their applications in biological research.

CO2. Develop Skills in Data Collection and Analysis

- Understand experimental design, sampling methods, and data interpretation in life sciences.

CO3. Apply Descriptive and Inferential Statistical Methods

- Learn measures of central tendency, dispersion, hypothesis testing, and probability distributions.

Bioinformatics Objectives:

CO1. Understand the Principles of Bioinformatics

- Learn the role of bioinformatics in genomics, proteomics, and systems biology.

CO2. Analyze Biological Databases and Sequence Alignment

- Study DNA, RNA, and protein sequence analysis using tools like BLAST, FASTA, and multiple sequence alignment.

CO3. Learn Computational Methods for Gene and Protein Analysis

- Understand phylogenetic analysis, motif discovery, and structural bioinformatics applications.

Unit-I	14 Lectures
Microscopy — Light, Phase contrast, fluorescence and Electron microscopy. Centrifugation technique. Principles types & separation of biological molecules.	
Unit-II	12 Lectures
Chromatography and Electrophoresis Chromatography: Principles and applications, Principle and application of electrophoresis. Agarose gel electrophoresis. Blotting: Southern, Western and Northern Blotting.	
Unit-III	10 Lectures
Spectrophotometry- Principle and Application UV and Visible Spectrophotometry , Colorimetry Radio and Non radio labeling, Autoradiography	
Unit-IV	12 Lectures
Biostatistics- Introduction, Scope, application and use of statistic collection and classification of data summarization and presentation of data. Arithmetic mean, median, standard deviation. Probability, definition. Random variable and its distribution. Binomial probability distribution.	
Unit-V	16 Lectures
Basic Bioinformatics: Introduction to Internet, Search Engines (Google, Yahoo, Entrez/ etc) Biological Databases: Sequence databases (EMBL. GenBank, DDBJ. UNIPROT. TrEMBL).	

BOOKS:

1. Bioinformatics C.V.S. Murthy
2. The text book of Bioinformatics , Sharma, Munjal And Shankar
3. Basic Bioinformatics, S. Ignacimuthu , S. J.
4. Biostatistics, B. Prasad
5. Biostatistics, P. N Arora

BIOTECHNOLOGY-IVPRACTICALS

MAX. MARKS: 50

No. of Laboratory per Week: 06 Hours

- Separation of amino acids by TLC
- Separation of leaf pigments by Paper chromatography.
- Estimation of hemoglobin.
- RBC counting by haematocytometer.
- WBC counting by Differential/ or total cell count.
- Measurement of bleeding and clotting time.
- Measurement of Hemin Crystals.
- Estimation of beta carotene in carrots.
- Estimation of ascorbic acid in lemon juice.
- Determination of iodine number of fat sample.
- Determination of phosphorus content in plant material (Colorimetric method).
- Computer Input and Output devices
- Prepare a Mark sheet of your class Subjects
- Prepare a bar chart, pie chart for analysis of Election Result.
- Exercise based on power point presentation.
- Design a presentation illustrating insertion of pictures , word art & clip art
- Use MS Word to insert a table into document.
- Problem based on Mean, Median, Mode.
- Hardy Weinberg Law applied on Population Genetics.
- Problem based on Probability.
- Exercise based on standard Deviation.
- Biological data resources and data retrieval

BSC-402–Environmental Studies-II

MAX.MARKS: 50

No.of Lectures per Week: 02 Hours

The Question Paper will contain questions equally distributed in all Units. The Internal Choice will be given in all Questions.

Course Objectives of Environmental Science

The **Environmental Science** course aims to provide students with a comprehensive understanding of the environment, ecological processes, and human impact on natural systems. The key objectives include:

CO1. Explore Waste Management and Sustainable Practices

- a. Study solid waste disposal, wastewater treatment, and recycling techniques to promote sustainability.

CO2. Analyze Environmental Laws and Policies

- b. Understand national and international environmental laws, treaties, and policies for environmental protection.

CO3. Examine Human Population and Environmental Impact

- c. Study population growth, urbanization, and their effects on natural resources and ecosystems.

CO4. Understand Renewable Energy and Conservation Strategies

- d. Explore alternative energy sources such as solar, wind, and bioenergy for sustainable development.

CO5. Apply Environmental Science Concepts to Real-World Problems

<u>Unit-I</u>	<u>12 Lectures</u>
Environmental pollution: types, causes, effects and controls; Air, water, soil and noise Pollution.	
<u>Unit-II</u>	<u>12 Lectures</u>
Climate change, global warming, ozone layer depletion, acid rain and impacts on human Communities and agriculture.	
<u>Unit-III</u>	<u>14 Lectures</u>
Solid waste management: Control measures of urban and industrial waste, special reference e-waste, Biomedical waste.	
<u>Unit-IV</u>	<u>12 Lectures</u>
Human Population and the Environment: population growth, population explosion, Family Welfare Programme.	
<u>Unit-V</u>	<u>14 Lectures</u>
Environmental Laws: The Environment (Protection) Act, 1986; The Air (Prevention and Control of Pollution) Act, 1981; The Water (Prevention and Control of Pollution) Act 1974; Forest (Conservation) Act, 1980; • The wildlife Protection Act, 1972	

BSC-403–ENTREPRENEURSHIP DEVELOPMENT-II

MAX.MARKS:50

No.of Lectures per Week: 02 Hours

The Question Paper will contain questions equally distributed in all Units. The Internal Choice will be given in all Questions.

Course Objectives of Entrepreneurship

The **Entrepreneurship** course aims to equip students with the knowledge, skills, and mindset required to start, manage, and grow a successful business. The key objectives include:

CO1. Understand the Fundamentals of Entrepreneurship

- Learn the definition, scope, and importance of entrepreneurship in economic development.

CO2. Explore Entrepreneurial Mindset and Characteristics

- Develop creativity, innovation, risk-taking ability, and problem-solving skills essential for entrepreneurs.

CO3. Identify Business Opportunities and Market Research

- Learn how to analyze market trends, identify business opportunities, and conduct feasibility studies.

CO4. Understand Business Planning and Strategy

- Develop a business model, draft a business plan, and formulate strategies for business success.

CO5. Learn About Funding and Financial Management

- Need – Sources of Finance, Term Loans, Capital Structure,
- Financial Institution, Financial Management for Project —Financial institution and their role,
- Capital estimation and arrangement. Cost and price determination and accounting management.
- Problem of entrepreneur — Problem relating Capital,
- Problem relating Registration , administration problem and how to overcome from above problems.
- Sickness in small Business – Concept, Magnitude, Causes and Consequences

TEXT BOOKS:

- Donald F Kuratko, “Entrepreneurship – Theory, Process and Practice”, 9 th Edition, Cengage Learning, 2014.
- Khanka. S.S., “Entrepreneurial Development” S.Chand & Co. Ltd., Ram Nagar, New Delhi, 2013.

BSC-501–BIOTECHNOLOGY-V: MOLECULAR BIOLOGY AND GENETIC ENGINEERING

MAX.MARKS:40+10

No. of Lectures per Week: 02 Hours

The Question Paper will contain questions equally distributed in all Units. The Internal Choice will be given in all Questions.

Course Objectives of Molecular Biology

The **Molecular Biology** course aims to provide students with a deep understanding of the molecular mechanisms that govern cellular processes, gene regulation, and biomolecular interactions. The key objectives include:

CO1. Understand the Molecular Basis of Life

- Learn the structure and function of DNA, RNA, and proteins and their roles in cellular processes.

CO2. Explore DNA Replication, Repair, and Recombination

- Study the molecular mechanisms of DNA replication, mutation repair pathways, and genetic recombination.

CO3. Understand Gene Expression and Regulation

- Analyze the processes of transcription, translation, and post-transcriptional modifications in prokaryotes and eukaryotes.

CO4. Examine Molecular Mechanisms of Genetic Control

- Explore epigenetic modifications, operon systems, and regulatory proteins involved in gene expression.

CO5. Analyze Protein Synthesis and Post-Translational Modifications

- Study the molecular machinery of ribosomes, tRNA, and protein folding pathways.

<u>Unit-I</u>	<u>12 Lectures</u>
DNA and RNA, Chemical Structure, Types and Properties, Experimental Proof of DNA as genetic material. DNA Replication. Types, Experimental proof of semi conservative replication, Replicon- Concept. Proteins and enzymes involved in replication in prokaryotes and eukaryotes, Modes of DNA replication. Unidirectional, Bidirectional, Types of DNA replication. Y shaped, rolling circle mechanism.	
<u>Unit-II</u>	<u>12 Lectures</u>
Eukaryotic chromosomal organization, Euchromatin, Heterochromatin. Chromatin structure. Nucleosomes, histone and non-histone proteins, histone modifications.	
<u>Unit-III</u>	<u>14 Lectures</u>
Origin of life: Classical experiments and current concepts. Evolution of biological macromolecules, Evolution of early forms, Mendelian genetics: Mendel's Law, Chromosomal basis of heredity, Chromosomal analysis, allelic variation, dominance. Linkage and crossing over.	
<u>Unit-IV</u>	<u>12 Lectures</u>
Introduction to Recombinant DNA technology, Scope & importance. Gene cloning using PCR, Introduction to Restriction endonuclease, DNA transfer techniques, Vectors and their types: Plasmids, Phagemids, Cosmids	
<u>Unit-V</u>	<u>14 Lectures</u>
Plasmids Types Properties and cloning vectors. Mutation, Types of mutations; Point mutation (Base pair change, frame shift. deletion). Transcription, translation in prokaryotes and eukaryotes. Operon Concept (lac and trp).	

BOOKS:

- Molecular Biology of the cell, 2002: Albert's et al
- The cell: A molecular approach: J.M. Cooper
- Cell biology: P.S. Verma and V.K. Agarwal
- Cell and Molecular Biology: P.K. Gupta
- Experiments in Biotechnology: Nighojkar and Nighojkar
- A practical book of Molecular Biology and Immunology; 2017: P.K. Singh *et al*

BIOTECHNOLOGY-V PRACTICALS

MAX.MARKS:50

No. of Laboratory per Week: 06 Hours

1. Chromosomal DNA isolation from Plant cells.
2. Chromosomal DNA isolation from Animal cells.
3. Genomic DNA isolation from Micro-Organisms.
4. Analysis of isolated DNA by Agarose gel electrophoresis.
5. Spectrophotometric analysis of DNA and DNA melting.
6. UV as a physical mutagen
7. Gradient Plate Technique
8. Estimation of DNA using diphenylamine method.
9. Estimation of RNA using orcinol method.
10. Isolation of RNA from Yeast.
11. Isolation of plasmid DNA from bacteria.
12. Effect of UV radiation on microbial cell
13. Demonstration of repair mechanism *in* microbes.
14. Bacteriophage and determination of latent period of infection
15. Isolation of total RNA from Plant tissue by SDS phenol method.
16. Elution of DNA from agarose gel band.
17. Transformation in E-coli cell.
18. Growth of plant tissue into undifferentiated mass of callus.
19. Preparation of animal cell culture media.
20. Separation and culture of lymphocyte from blood.
21. Demonstration of fermentor.
22. Preparation of wine.
23. Extraction of citric acid from *A.spergilluv*.
24. Production of ethanol by yeast.
25. Demonstration of PCR.

BSC-502–BIOTECHNOLOGY FOR FORENSIC SCIENCE

MAX. MARKS:50

No. of Lectures per Week: 02Hours

The Question Paper will contain questions equally distributed in all Units. The Internal Choice will be given in all Questions.

Course Objectives of Forensic Science

The **Forensic Science** course aims to provide students with a fundamental understanding of scientific principles and techniques used in crime investigation and legal proceedings. The key objectives include:

CO1. Understand the Basics of Forensic Science

- Learn the history, scope, and significance of forensic science in criminal investigations.

CO2. Explore Crime Scene Investigation Techniques

- Study procedures for crime scene documentation, evidence collection, and preservation.

CO3. Analyze Physical and Biological Evidence

- Learn techniques for analyzing fingerprints, bloodstains, DNA, hair, fibers, and other trace evidence.

CO4. Understand Forensic Toxicology and Drug Analysis

- Study the detection and effects of drugs, poisons, and alcohol in criminal cases.

CO5. Learn Forensic DNA Profiling and Genetic Analysis

- Understand the role of DNA sequencing, PCR, and STR analysis in identifying individual

Syllabus

- Basic of Forensic Science: Introduction, Definition, need, signification and scope of Forensic Science.
- Principles of Forensic Science, multi professional and multi personal aspects of forensic science.
- Domains in Forensic Science: Forensic **Biology**, Forensic Medicine, Forensic Toxicology, Forensic Osteology and Odontology, Forensic Anthropology, Wild life Forensic, DNA profiling, Computer Forensic etc.
- Ethical issue in Forensic Science
- Organization set up of Forensic Science Laboratory

BSC-503–Intellectual Property Rights

MAX.MARKS:50

No.of Lectures per Week: 02Hours

The Question Paper will contain questions equally distributed in all Units. The Internal Choice will be given in all Questions.

Course Objectives of Intellectual Property Rights (IPR)

The **Intellectual Property Rights (IPR)** course aims to provide students with a comprehensive understanding of intellectual property laws, their significance, and their application in various fields. The key objectives include:

CO1. Understand the Fundamentals of Intellectual Property (IP)

- Learn the concept, history, and importance of intellectual property rights in innovation and business.

CO2. Explore Different Types of Intellectual Property

- Study patents, copyrights, trademarks, trade secrets, geographical indications, and industrial designs.

CO3. Examine Patent Laws and Filing Procedures

- Understand the process of patent application, examination, and grant at national and international levels.

CO4. Analyze Copyright Laws and Protection Mechanisms

- Learn about copyright policies, fair use, and protection of literary, artistic, and digital works.

CO5. Understand Trademark Registration and Brand Protection

- Explore the significance of trademarks, their registration process, and infringement issues.

- Introduction to Intellectual Property, Copyright, Related Rights,
- Types of Intellectual Property and legislations covering IPR in India:-Patents, Copyrights, Trademark.
- Industrial design and Trade secrets.
- Protection of plant varieties and Farmers' Right Act, Methods of protection of plant and plant products,
- Essentialities of plant protection.
- Classification of patents by WIPO, Categories of Patent Special Patents, Patenting Biological products

Course Outcomes of Intellectual Property Rights (IPR)

Upon successful completion of the **Intellectual Property Rights (IPR)** course, students will be able to:

CO1. Demonstrate an Understanding of Intellectual Property (IP) Concepts

- Explain the significance of IPR in protecting innovations, creativity, and business assets.

CO2. Differentiate Various Types of Intellectual Property

- Identify and describe patents, copyrights, trademarks, trade secrets, geographical indications, and industrial designs.

CO3. Apply Patent Laws and Filing Procedures

- Understand the process of patent filing, examination, grant, and maintenance at national and international levels.

CO4. Analyze Copyright Protection and Fair Use Policies

- Explain the legal aspects of copyright protection in literary, artistic, and digital works.

CO5. Understand Trademark Laws and Brand Protection Strategies

- Evaluate the importance of trademarks and their role in brand identity and business growth.

BSC-601–BIOTECHNOLOGY-VI

APPLIED BIOTECHNOLOGY

MAX.MARKS:40+10

No.of Lectures per Week: 02 Hours

The Question Paper will contain questions equally distributed in all Units. The Internal Choice will be given in all Questions.

Course Objectives of Applied Biotechnology

CO1. Understand the Fundamentals of Biotechnology

- Learn the basic concepts, tools, and techniques used in modern biotechnology.

CO2. Explore Genetic Engineering and Recombinant DNA Technology

- Study gene cloning, vector systems, gene expression, and CRISPR-based genome editing.

CO3. Analyze Applications of Biotechnology in Healthcare

- Understand the development of biopharmaceuticals, gene therapy, vaccines, and personalized medicine.

CO4. Examine Agricultural Biotechnology and Crop Improvement

- Learn about genetically modified organisms (GMOs), bio fertilizers, and pest-resistant crops.

CO5. Study Industrial Biotechnology and Bioprocessing Techniques

Unit-I	14 Lectures
Food Microbiology-Microbial contamination & Spoilage, Food preservation. Industrial Production of Penicillin..	
Unit-II	12 Lectures
Introduction to plant tissue culture, Nutritional requirements, In vitro culture. Single cell culture, Anther culture, Ovule culture, Somatic embryogenesis, Organogenesis Protoplast culture, Somatic hybridization, Genetic manipulation of plants using Agrobacterium tumefaciens	
Unit-III	10 Lectures
Immunity- Innate and Acquired, Cells of Immune system, Vaccines and its types .Antigens- Properties and types. Immunoglobulin- Structure, types and functions. ,Primary and Secondary response, History Equipment and materials for animal cell culture technology. Physical requirement for animal cell and their growth curve in culture. . Applications of animal biotechnology: Methods of Transfection and cell fusion of animal cells, Selectable markers, HAT selection, Transgenic animals, Stem cell culture., Bioreactors for large scale production of animal cells.	
Unit-IV	12 Lectures
Fermentation Technology, Primary and Secondary. Screening and Strain Improvement. Industrial Sterilization process, Scale-up and Harvest and Recovery. Types of fermentation — batch, continuous and fed batch process. Basic design of a fermenter and factors affecting fermentation, design. Types of fermenters.	
Unit-V	16 Lectures
Environment: Basic concept, Significance, Environmental pollution, Assessment of water quality, Treatment of waste-water — Primary, secondary and tertiary treatment. Bio fertilizers - Nitrogen fixers, PSB, Mycorrhiza and VAM	

BIOTECHNOLOGY-VI PRACTICALS

MAX. MARKS:50

No. of Laboratory per Week: 06 Hours

1. Effect of UV radiation on microbial cell
2. Demonstration of repair mechanism *in* microbes.
3. Bacteriophage **and** determination of latent period of infection
4. Elution of DNA from agarose gel band.
5. Transformation in E-coli cell.
6. Growth of plant tissue into undifferentiated mass of callus.
7. Preparation of animal cell culture media.
8. Separation and culture of lymphocyte from blood.
9. Demonstration of fermenter.
10. Preparation of wine.
11. Demonstration of PCR.

BSC-201: INFORMATION TECHNOLOGY AND APPLICATION

Introduction to Computers

Introduction, Characteristics of computers, Evolution of computers, Generation of Computers, Classification of Computers, The Computer System, Applications of Computers.

Input / Output devices and Memory

Introduction, Keyboard, Pointing Devices, Speech Recognition, Digital Camera, Scanners, Optical Scanners. Classification of Output, Printers, Plotters, Computer Output Microfilm (COM), Monitors, Audio Output, Projectors. Random Access Memory (RAM), Types of RAM, Read Only Memory (ROM), Types of ROM. Classification of Secondary Storage Devices.

Software Concepts

Introduction to Software, Relationship between Software and Hardware, System Software, Application Software and its types, Utility Software, Algorithm, Flowchart, Program, and Pseudo code (P-Code). Features of a Good Programming Language.

Data Communication and Computer Network

Introduction, Data Communication, Transmission Media, Multiplexing, Switching, Computer Network, Network Topologies, Communication Protocols, Network devices.

World Wide Web, Hypertext, Uniform Resource Locator, Web Browsers, IP Address, Domain Name, Internet Services Providers, Internet Security, Internet Requirements, Web Search Engine, Net Surfing, Internet Services

MS-Office – MS-Word, MS-Excel, Ms-Power Point.

Text Books:

1. V. Rajaraman, Fundamentals Of Computers, 3rd Edition , PHI Publications
2. Nasib S. Gill, Essentials of Computer & Network Technology, Khanna Publications.
3. Deepak Bharihoke, Fundamentals of Information Technology, Excel Books.

Reference Book:

1. Rajaraman V. – Fundamental of Computers, Prentice Hall of India Pvt. Ltd., New Delhi – 2nd edition, 1996.

BSC-202: PROGRAMMING IN C

Fundamentals of C: History of Programming language. Identifier and keywords - data types - constants - Variables - Declarations -Expressions - Statements - Arithmetic, Unary, Relational and logical, Assignment and Conditional Operators - Library functions. Simple C programs - Flow of control - if, if-else, while, do-while, for loop, Nested control structures - Switch, break and continue, goto statements - Comma operator.

Functions -Definition - prototypes –types-Passing arguments–Recursion and its types- Storage Classes - Automatic, External, Static, Global and Register Variables.

Arrays - Defining and Processing - Passing arrays to functions - Multi-dimension arrays - Arrays and Strings.

Structures and unions - User defined data types - Passing structures to functions - Self- referential structures - Unions - Bit wise operations.

Pointers - Declarations - Passing pointers to Functions - Operation on Pointers - Pointer and Arrays.

Files: File Handling in C Using File Pointers, Open a file using the function fopen (), Close a file using the function fclose (), Input and Output using file pointers, Character Input and Output in Files, String Input / Output Functions, Formatted Input / Output Functions, Block Input / Output Functions, Sequential Vs Random Access Files, Positioning the File Pointer.

Text Book:

1. E. BalaguruSwamy - ANSI C Programming Language, 2nd Edition, PHI, 1988.
2. Kanetkar Y., Let us C, BPB Pub., New Delhi, 1999.
3. ReemaThareja - Programming in C

Reference Book:

1. H. Schildt, C: The Complete Reference, 4th Edition, TMH Edition, 2000.
2. Byron Gotlfried – C Programming; Oxford University Press

BSC-203: DATA STRUCTURE USING C

Primitive and Composite Data Types, Time and Space Complexity of Algorithms, Stack and Primitive Operation on Stack. Applications- Infix, Postfix, Prefix and Recursion. Queues, Primitive Operations on Queues, Circular Queue, De Queue and Priority Queue.

Linked List: Basic Operation on Linked List, Circular Linked List, Doubly Linked List, Linked Representation of Stack and Queue, Application of Linked List.

Trees: Basic Terminology, Binary Trees, Tree Representation as Array and Linked List, Basic Operation on Binary Tree, Traversal of Binary Tree – In Order, Preorder, Post Order, Application of Binary Tree, Threaded Binary Tree, B-Tree and Height Balance Tree(AVL).

Sorting & Searching: Sequential Search, Binary Search, Insertion Sort, Selection Sort, Quick Sort, Bubble Sort, Heap Sort, and Comparison of Sorting Methods.

Graph: Introduction to Graphs, Definition, Terminology, Directed, Undirected, Weighted Graph, Representation of Graphs, Graph Traversal – Depth First and Breadth First, Spanning Trees, Minimum Spanning Trees, Shortest Path Algorithm.

Text Book:

1. Expert Data Structure with 'C' By R.B Patel (Khanna Book Publishing Co.(P))
2. Data structure By Lipschutz (Tata McGraw Hill)
3. Data Structure By Yashvant Kanitkar (BPB)

Reference Book:

1. An Introduction to Data Structures with Applications, By Jean-Paul Tremblay, Paul G.Sarerson (Tata McGraw Hill)
2. Data Structure Using C and C++ By Yedidyahlangsam, Moshe J.Augenstein, Arora M. Tenenbaum (Prentice- Hall India)

BSC-204 OBJECT ORIENTED PROGRAMMING USING JAVA

Introduction to java: evolution, features, comparison with C and C++; Java program structure; tokens, keywords, constants, variables, data types, type casting, statements, Operators and Expression; Conditional Statements and Loop Statements.

Class: syntax, instance variable, class variables, methods, constructors, overloading of constructors and methods. Arrays, Strings and Vectors.

Inheritance: types of inheritance, use of super, method overriding, final class, abstract class, wrapper classes. Interface, Packages and visibility controls.

Errors and Exceptions: Types of errors, Exception classes, Exception handling in java, use of try, catch, finally, throw and throws. Taking user input, Command line arguments. **Multithreaded Programming:** Creating Threads, Life cycle of thread, Thread priority, Thread synchronization, Inter-thread communication, implementing the Runnable Interface;

Applet: Applet Life Cycle, Applet Tag, Adding Applet to HTML File; Passing Parameters to Applets, Getting Input from User. **AWT :** AWT Classes, Working With Frame Windows, Working With Graphics, Working With Colour, Adding And Removing Controls, Responding To Controls, Labels, Buttons, Checkbox, Checkbox Group, Choice Control, Lists, Text Field, Text Area. Menus, Dialog Box, Handling Events.

Text Book:

1. Java: A Beginner's Guide, Sixth Edition: A Beginner's Guide by Herbert Schildt, McGraw-Hill
Osborne Media
2. Programming in JAVA By E. Balagurusamy (TMH)
3. JAVA 2 programming Black Book By Steven Holzner et al. (Dreamtech Press)

Reference Book:

1. The Complete reference Java Ninth Edition By Herbert Schildt (Tata McGraw Hill)
2. Core Java Volume I--Fundamentals (9th Edition) by Cay S. Horstmann, Gary Cornell, Prentice Hall

BSC-205: DATABASE MANAGEMENT SYSTEM

Introduction: Characteristics of database approach, Advantages, Database system architecture, Overview of different types of Data Models and data independence, Schemas and instances, Database languages and interfaces; E-R Model : Entities, Attributes, keys, Relationships, Roles, Dependencies, E-R Diagram.

Introduction to Relational model, Constraints: Domain, Key, Entity integrity, Referential integrity; Keys: Primary, Super, Candidate, Foreign; Relational algebra: select, project, union, intersection, cross product, different types of join operations.

SQL: Data Types, statements: select, insert, update, delete, create, alter, drop; views, SQL algebraic operations; Stored procedures: Advantages, Variables, creating and calling procedures, if and case statements, loops, Functions, Triggers.

Normalization: Definition, Functional dependencies and inference rules, 1NF, 2NF, and 3NF; Transactions processing: Definition, desirable properties of transactions, serial and non-serial schedules, concept of serializability, conflict-serializable schedules.

Concurrency Control: Two-phase locking techniques, dealing with Deadlock and starvation, deadlock prevention protocols, basic timestamp ordering algorithm; Overview of database recovery techniques; concept of data warehousing.

Text Book:

1. Database System Concepts By Korth, Silberschatz, Sudarshan (Mcgraw Hill)
2. An Introduction to Database Systems By Bipin C. Desai (Galgotia Publication.)
3. SQL, PL/SQL Programming By Ivan Bayross (BPB)
4. Commercial Application Development Using Oracle Developer 2000 By Ivan Bayross (BPB)

Reference Book:

1. Fundamentals of Database Systems, Ramez A. Elmasri, Shamkant Navathe, 5th Ed(Pearson)

BSC-206: PYTHON PROGRAMMING

Overview of Programming: Structure of a Python Program, Python Interpreter, Using Python as calculator, Python shell, Indentation. Atoms, Identifiers and keywords, Literals, Strings, Operators (Arithmetic operator, Relational operator, Logical or Boolean operator, Assignment, Operator, Ternary operator, Bit wise operator, Increment or Decrement operator).

Creating Python Programs: Input and Output Statements, Control statements (Branching, Looping, Conditional Statement, Exit function, Difference between break, continue), Defining Functions, default arguments, Errors and Exceptions.

Iteration and Recursion: Conditional execution, Alternative execution, Nested conditionals, The return statement, Recursion, Stack diagrams for recursive functions, Multiple assignment, The while statement, Implementing 2-D matrices.

Strings and Lists: String as a compound data type, Length, Traversal and the for loop, String slices, String comparison, Looping and counting, List values, Accessing elements, List length, List membership, Lists and for loops, List operations, List deletion. Cloning lists, Nested lists .

Object Oriented Programming: Introduction to Classes, Objects and Methods, Standard Libraries. Overview of stacks and queues.

Text Books:

1. T. Budd, Exploring Python, TMH, 1st Ed, 2011
2. Introduction to computation and programming python, by John Guttag, MIT Press.
3. Learning Python, Lutz and Ascher, O'Reilly publications

Web Resources:

1. http://files.swaroopch.com/python/byte_of_python.pdf
 2. <https://www.cs.uky.edu/~keen/115/Haltermanpythonbook.pdf>
 3. <http://greenteapress.com/thinkpython/thinkpython.pdf>
- Python tutorials: <https://docs.python.org/3/tutorial/index.html>

BSC- 301 – PHARMA CHEMISTRY- I

INORGANIC CHEMISTRY

Scope:

This subject deals with the monographs of inorganic drugs and pharmaceuticals. General discussion on the following inorganic compounds including important physical and chemical properties, medicinal and pharmaceutical uses and storage conditions.

Unit-I

Impurities in pharmaceutical substances: History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals,

Acids, Bases and Buffers: Acid-base theories, Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity. Boric acid, Ammonium hydroxide, Hydrochloric acid and official buffers.

UNIT-II

Gastrointestinal agents

Acidifiers: Ammonium chloride and Dil. HCl

Antacid: Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate, Aluminum hydroxide gel, Magnesium hydroxide mixture, Aluminum phosphate, Calcium carbonate, Combinations of antacid preparations.

Cathartics: Magnesium sulphate, Sodium potassium tartrate

Topical agents

Antimicrobials & Astringents: Mechanism, classification, Potassium permanganate, Hydrogen peroxide, Chlorinated lime, Iodine and its preparations, Borax, Silver nitrate, Ammoniated mercury, Mercuric oxide, Zinc Sulphate, Potash Alum

UNIT III

Major extra and intracellular electrolytes

Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride & its preparation, Potassium chloride, Calcium gluconate, Sodium lactate injection, Potassium citrate and Oral Rehydration Salt (ORS), Physiological acid base balance.

UNIT IV

Expectorants & Emetics

Potassium iodide, Ammonium chloride, Copper sulphate, Antimony potassium tartrate

Haematinics

Ferrous sulphate, Ferrous gluconate

Poison and Antidote

Sodium thiosulphate, Activated charcoal, Sodium nitrite

UNIT V

Radiopharmaceuticals

Radio activity, Measurement of radioactivity, Properties of α , β , γ radiations, Half-life, radio isotopes and study of radio isotopes - Sodium iodide I131 , Storage conditions, precautions & pharmaceutical application of radioactive substances. Radio opaque contrast media- Barium sulfate.

PRACTICAL

1. Limit test for Chloride, Sulfate, Arsenic, Iron and Heavy metals.
2. Identification tests for inorganic compounds particularly drugs and pharmaceuticals.
3. Estimation of Fe(II) ions by titrating it with $K_2Cr_2O_7$.
4. Estimation of Cu(II) ions iodometrically using $Na_2S_2O_3$.
5. Estimation of sodium carbonate and sodium bicarbonate present in a mixture.

Recommended Books

6. Inorganic pharmaceutical chemistry, Anand & Chatwal.
7. Vogel's Quantitative Chemical Analysis, A.I. Vogel, Prentice Hall, 6th Edition.
8. J.D. Lee: A new Concise Inorganic Chemistry, EL.B.S.
9. F.A. Cotton & G. Wilkinson: Basic Inorganic Chemistry, John Wiley.
10. Douglas, McDaniel and Alexander: Concepts and Models in Inorganic Chemistry, John Wiley

BSC- 302 – PHARMA CHEMISTRY- II

BIO-CHEMISTRY & METABOLISM

Unit-I

Amino acid & Proteins: Structure and properties of Amino acids, Types of Proteins and their Classification, Forces stabilizing protein structure and shape. Different levels of structural organization of proteins, Fibrous and globular proteins. Carbohydrates: Structure, Function and properties of Monosaccharides, Disaccharides and Polysaccharides. Homo & Hetero polysaccharides, Muco-polysaccharides, Bacterial cell wall polysaccharides, Glycoproteins and their biological functions.

UNIT-II

Lipids: Structure and functions Classification, nomenclature and properties of fatty acids, essential fatty acids. Phospholipids, Sphingolipids, Glycolipids, Cerebrosides, Gangliosides, Prostaglandins, Cholesterol.

UNIT-III

Nucleic acids: Structure and functions: Physical & chemical properties of Nucleic acids, Nucleosides & Nucleotides, Purines & Pyrimidines. Biologically important nucleotides, Double helical model of DNA structure and forces responsible for A, B & Z DNA.

UNIT-IV

Enzymes: Nomenclature and classification of Enzymes, Holoenzyme, apoenzyme, Cofactors, coenzyme, prosthetic groups, Enzyme activity, Specific activity, Common feature of active sites, Enzyme specificity.

UNIT-V

Carbohydrates Metabolism: Reactions, energetic and regulation. Glycolysis: Fate of pyruvate under aerobic and anaerobic conditions. Pentose phosphate pathway and its significance, Gluconeogenesis, Glycogenolysis and glycogen synthesis. TCA cycle, Electron transport chain, Oxidative phosphorylation, Beta-oxidation of fatty acids.

PRACTICAL

1. To study activities of any enzyme under optimum conditions.
2. To study the effect of pH, temperature on the activity of salivary amylase enzyme.
3. Determination of pH optima, temperature optima, Km value, Vmax value, Effect of inhibitor (Inorganic phosphate) on the enzyme activity.
4. Estimation of blood by glucose oxidase method. item Principles of Colorimetry: (i) Verification of Beers Lambert's law, estimation of protein. (ii) To study relation between absorbance and % transmission.
5. Preparation of buffers.
6. Separation of Amino acids by paper chromatography.
7. Qualitative tests for Carbohydrates and lipids.
8. Qualitative estimation of proteins.

Recommended Books

1. Nelson, D.L., Cox, M.M. (2004) Lehninger Principles of Biochemistry, 4th Edition, WH Freeman and Company, New York, USA.
2. Berg, J. M., Tymoczko, J. L. and Stryer, L. (2006). Biochemistry. VI Edition. W.H Freeman and Co.
3. Harper's Illustrated Biochemistry (Harper's Biochemistry) by Robert K. Murray, Darryl K. Granner, Peter A. Mayes, and Victor W. Rodwell.
4. Fundamentals of Biochemistry. Life at the molecular level (Fourth Edition) by Donald Voet, Judith G. Voet and Charlotte. W. Pratt. Willey 2010.
5. Biophysical Chemistry, Principles & Techniques – Upadhyay, Upadhyay & Nath – Himalaya Publ.
6. Biochemistry, 4th edition by U Satyanarayana and U Chakrapani, Elsevier India

BSC- 303 – PHARMA CHEMISTRY- III

ORGANIC CHEMISTRY

Unit-I

Atomic Structure

Review of: Bohrs theory and its limitations, dual behaviour of matter and radiation, de- Broglies relation, Heisenberg Uncertainty principle. Hydrogen atom spectra. Quantum mechanics . Radial and angular parts of the hydrogenic wave functions (atomic orbitals) and their variations for 1s, 2s, 2p, 3s, 3p and 3d orbitals (Only graphical representation). Significance of quantum numbers. Spin quantum number (s) and magnetic spin quantum number (ms). Rules for filling electrons in various orbitals, Electronic configurations of the atoms. Stability of half-filled and completely filled orbitals, concept of exchange energy. Relative energies of atomic orbitals.

Unit-II

Chemical and Molecular Structure

Ionic Bonding: General characteristics of ionic bonding. Energy considerations in ionic bonding, lattice energy and solvation energy and their importance in the context of stability and solubility of ionic compounds. Statement of Born-Land equation for calculation of lattice energy, Born- Haber cycle and its applications, polarizing power and polarizability. Fajans rules, ionic character in covalent compounds, dipole moment .Covalent bonding: VB Approach: Shapes of some inorganic molecules and ions on the basis of VSEPR and hybridization with suitable examples of linear, trigonal planar, square planar, tetrahedral, trigonal bipyramidal and octahedral arrangements. Concept of resonance and resonating structures in various inorganic and organic compounds.

Unit- III

Fundamentals of Organic Chemistry

Physical Effects, Electronic Displacements: Inductive Effect, Electromeric Effect, Resonance and Hyper conjugation. Cleavage of Bonds: Homolysis and Heterolysis. Structure, shape and reactivity of organic molecules: Nucleophiles and electrophiles. Reactive Intermediates: Carbocations, Carbanions and free radicals. Strength of organic acids and bases. Aromaticity: Huckels rule.

Unit-IV

Stereochemistry

Conformations with respect to ethane, butane and cyclohexane. Fischer representations. Concept of chirality (upto two carbon atoms). Configuration: Geometrical and Optical isomerism; Enantiomerism, Diastereomerism and Meso compounds). D and L; cis-trans nomenclature. Racemic modification and resolution of racemic mixture.

Unit- V

Aliphatic Hydrocarbons

Preparations & reactions Alkanes: (Upto 5 Carbons). Preparation: Catalytic hydrogenation, Wurtz reaction, Kolbes synthesis, from Grignard reagent. Reactions: Free radical Substitution: Halogenation. Alkenes: (Upto 5 Carbons) Preparation: Elimination reactions: Dehydration of alkenes and dehydro-halogenation of alkyl halides (Saytzeffs rule); cis alkenes (Partial catalytic hydrogenation) Birch reduction. Reactions: cis-addition (alk. KMnO_4) and trans-addition (bromine), Markownikoffs and anti-Markownikoffsrule, Hydration, Ozonolysis, Alkynes: (Upto 5 Carbons) Preparation: Acetylene from CaC_2 and conversion into higher alkynes; by dehalogenation of tetra halides and dehydrohalogenation of vicinal-dihalides. Reactions: formation of metal acetylides, addition of bromine and alkaline KMnO_4 , ozonolysis.

PRACTICAL

1. Detection of extra elements (N, S, Cl, Br, I) in organic compounds (containing upto two extra elements).
2. Experiments involving laboratory techniques - Recrystallization, Steam distillation.

Recommended Books

1. Vogels Qualitative Inorganic Analysis, A.I. Vogel, Prentice Hall, 7th Edition.
2. Vogels Quantitative Chemical Analysis, A.I. Vogel, Prentice Hall, 6th Edition.
3. Textbook of Practical Organic Chemistry, A.I. Vogel , Prentice Hall, 5th edition.
4. Practical Organic Chemistry, F. G. Mann. & B. C. Saunders, Orient Longman, 1960.

BSC- 304 – PHARMA CHEMISTRY- IV

PHARMACEUTICAL ANALYSIS

Scope

This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs.

Unit-I

a) **Pharmaceutical analysis** : Definition and scope

- i) Different techniques of analysis
- ii) Methods of expressing concentration
- iii) Primary and secondary standards.
- iv) Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate
- v) **Errors**: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures.

UNIT-II

Acid base titration

Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases neutralization curves.

Non aqueous titration

Solvents, acidimetry and alkalimetry titration and, estimation of Sodium benzoate and Ephedrine HCl

UNIT-III

Complex metric titration

Classification, metal ion indicators, masking and damasking reagents, estimation of Magnesium sulphate, and calcium gluconate.

Gravimetry

Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate. Basic Principles, methods and application of diazotization titration

UNIT-IV

Redox titrations

- (a) Concepts of oxidation and reduction
- (b) Types of redox titrations (Principles and applications) Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, and Titration with potassium iodate.

UNIT-V

Electrochemical methods of analysis

Conductometry

Introduction, Conductivity cell, Conductometric titrations, applications

Potentiometry

Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.

Polarography

Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications.

PRACTICAL

I. Preparation and standardization of

- (1) Sodium hydroxide
- (2) Sulphuric acid
- (3) Sodium thiosulfate
- (4) Potassium permanganate
- (5) Ceric ammonium sulphate

II. Assay of the following compounds along with Standardization of Titrant

- (1) Ammonium chloride by acid base titration
- (2) Ferrous sulphate by Cerimetry
- (3) Copper sulphate by Iodometry
- (4) Calcium gluconate by complexometry
- (5) Hydrogen peroxide by Permanganometry

Recommended Books

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
5. John H. Kennedy, Analytical chemistry principles

BSC- 305 – PHARMA CHEMISTRY- V

PHARMACEUTICAL QUALITY ASSURANCE

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

UNIT – I

Quality Assurance and Quality Management concepts

Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM)

Definition, elements, philosophies

ICH Guidelines

Purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD)

Definition, overview, elements of QbD program, tools

ISO 9000 & ISO14000

Overview, Benefits, Elements, steps for registration

UNIT - II

Organization and personnel

Personnel responsibilities, training, hygiene and personal records.

Premises

Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials

Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT – III

Quality Control

Quality control test for containers, rubber closures and secondary packing materials.

Good Laboratory Practices

General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities.

UNIT – IV

Complaints

Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Document maintenance in pharmaceutical industry

Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT – V

Calibration and Validation

Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Recommended Books

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2 nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh.
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

BSC- 306 – PHARMA CHEMISTRY- VI

PHARMACEUTICAL REGULATORY SCIENCE

Scope

This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Unit I

New Drug Discovery and development Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II

Regulatory Approval Process Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

Unit III

Registration of Indian drug product in overseas market Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD) research.

Unit IV

Clinical trials Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials.

Unit V

Regulatory Concepts Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book.

Recommended Books

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

CO PO Mapping Metrics

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	2	2	3	0	2	2	3	0	1	0
CO2	3	1	1	2	0	3	1	2	3	1
CO3	2	3	1	1	3	0	2	1	3	2
CO4	1	1	2	1	1	1	1	3	2	3
CO5	1	2	1	1	3	2	1	1	1	1
	1.8	1.8	1.6	1	1.8	1.6	1.6	1.4	2	1.4

CO PO Mapping Metrics

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	1	3	2	2	1	1	1	0	2	2
CO2	2	0	1	1	0	2	2	2	1	1
CO3	3	4	1	2	2	1	3	1	2	2
CO4	1	2	3	1	1	2	1	2	2	1
CO5	2	1	0	3	1	1	0	3	1	1
AVR	1.8	2	1.4	1.8	1	1.4	1.4	1.6	1.6	1.4

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	1	3	1	1	1	1	1	0	2	2
CO2	2	1	1	2	1	2	2	1	1	1
CO3	3	3	1	1	1	2	2	2	2	2
CO4	1	1	3	1	0	2	1	2	2	1
CO5	1	1	0	3	2	1	0	3	1	1
AVR	1.6	1.8	1.4	1.6	1	1.6	1.2	1.6	1.6	1.4

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	3	3	3	0	2	2	3	0	1	0
CO2	2	2	1	2	0	3	1	2	3	1
CO3	2	3	0	1	3	0	2	1	3	2
CO4	1	1	2	1	1	1	1	3	2	3
CO5	1	2	1	1	3	2	1	1	1	1
	1.8	2.0	1.5	1	1.8	1.6	1.6	1.4	2	1.4

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	1	3	1	2	1	0	1	0	2	2
CO2	1	2	1	1	0	1	2	2	2	1

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	2	2	3	0	2	2	3	0	1	0
CO2	3	1	1	2	0	3	1	2	3	1
CO3	2	3	1	1	3	0	2	1	3	2
CO4	1	1	2	1	1	1	1	3	2	3
CO5	1	2	1	1	3	2	1	1	1	1
	1.8	1.8	1.6	1	1.8	1.6	1.6	1.4	2	1.4
CO3	2	1	3	3	2	1	1	1	1	2
CO4	1	1	1	1	1	2	1	2	1	1
CO5	2	1	0	1	1	1	0	3	1	1
AVR	1.4	1.6	1.4	1.6	1	1	1	1.6	1.4	1.4

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	2	1	2	1	1	1	1	0	2	2
CO2	1	2	1	1	1	1	2	1	1	1
CO3	3	2	1	2	2	2	2	2	2	2
CO4	1	1	3	1	0	2	1	2	2	1
CO5	1	1	0	3	2	1	0	3	1	1
AVR	1.6	1.4	1.4	1.6	1.2	1.4	1.2	1.6	1.6	1.4

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	1	3	1	2	1	0	1	0	2	2
CO2	1	2	1	1	0	1	2	2	2	1
CO3	2	1	3	3	2	1	1	1	1	2
CO4	1	1	1	1	1	2	1	2	1	1
CO5	2	1	0	1	1	1	0	3	1	1
AVR	1.4	1.6	1.4	1.6	1	1	1	1.6	1.4	1.4

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	3	1	2	1	1	1	1	0	2	2
CO2	1	2	2	2	1	0	2	1	1	1
CO3	0	1	1	2	2	2	2	2	2	2
CO4	1	1	3	1	0	2	1	2	1	1
CO5	1	1	0	3	2	1	0	2	1	1
AVR	1.2	1.2	1.4	1.8	1.2	1.2	1.2	1.4	1.4	1.4

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	3	1	2	1	1	1	1	0	2	2
CO2	2	2	2	2	2	0	2	1	1	1
CO3	1	1	1	3	2	3	2	2	2	2
CO4	1	2	3	1	3	2	2	2	2	1
CO5	1	1	2	3	2	2	0	2	1	1
AVR	1.6	1.4	1.4	2	2	1.6	1.4	1.4	1.6	1.4

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	3	1	2	1	1	1	1	0	2	2
CO2	2	2	2	2	2	0	2	1	1	1
CO3	1	1	1	3	2	3	2	2	2	2
CO4	1	2	3	1	3	2	2	2	2	1
CO5	1	1	2	3	2	2	0	2	1	1
AVR	1.6	1.4	1.4	2	2	1.6	1.4	1.4	1.6	1.4

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	3	1	2	1	1	1	1	0	2	2
CO2	2	2	2	2	2	0	2	1	1	1
CO3	3	2	0	3	2	3	2	2	2	2
CO4	1	2	3	2	2	2	1	3	2	1
CO5	1	1	2	1	2	2	0	2	1	1
AVR	2	1.6	1.4	1.8	1.8	1.6	1.2	1.6	1.6	1.4

CO PO Mapping Metrics

CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10
CO1	2	2	1	3	1	0	1	0	2	2
CO2	3	2	3	2	0	2	2	2	2	2
CO3	1	1	2	3	2	2	2	3	2	1
CO4	1	1	1	2	1	1	1	2	1	2
CO5	2	1	0	1	2	1	0	3	1	1
AVR	1.8	1.4	1.4	2.2	1.2	1.2	1.2	2	1.6	1.6


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