



ST ALOYSIUS COLLEGE (AUTONOMOUS)
MANGALURU

RE-ACCREDITED BY NAAC "A" GRADE

With a CGPA – 3.62 (3rd cycle)

COURSE STRUCTURE AND SYLLABUS

OF

M.Sc. Biotechnology
CHOICE BASED CREDIT SYSTEM (CBCS)

(2021 -22 BATCH ONWARDS)



Re-accredited by NAAC with 'A' Grade with CGPA 3.62/4
Recognised by UGC as "College with Potential for Excellence"
Conferred "College with "STAR STATUS" by DBT, Government of India.
Centre for Research Capacity Building under UGC-STRIDE

Date: 12-08-2021

NOTIFICATION

Sub: Syllabus of **M.Sc. Biotechnology** Under Choice Based Credit System.

Ref: 1. Decision of the Academic Council meeting held on 19-06-2021 vide Agenda No: 11(2021-22)
2. Office Notification dated 12-08-2021

Pursuant to the above, the Syllabus of **M.Sc. Biotechnology** under Choice Based Credit System which was approved by the Academic Council at its meeting held on 19-06-2021 is hereby notified for implementation with effect from the academic year **2021-22**.

PRINCIPAL

REGISTRAR

To:

1. The Chairman/Dean/HOD.
2. The Registrar
3. Library
4. PG Office

Preamble

St. Aloysius College ventured into the field of Biotechnology as the first College in Dakshina Kannada District to start an undergraduate course in the year 2001. The Management of St. Aloysius College took a major step of starting the post graduate course in the year 2002 under the affiliation of Mangalore University. Since 2007, the course is under the Autonomy Status of the College. The Department was recognized as a Centre for Research in Biotechnology under Mangalore University in 2009. Students enrolled for the PhD program since 2011. It presently has 9 PhD scholars. 8 students have been awarded PhD degree in Biotechnology from Mangalore University. The department of M.Sc. Biotechnology has strong research content, with 4 Ph.Ds; 2 recognized research guides for PhD, have to their credit several national and international publications and have received major and minor research projects from DST, BRNS and UGC. The Department is one among 17 institutions of Karnataka to be selected for the Govt. of Karnataka's (VGST) Biotechnology Skill Enhancement Programme (BiSEP) with specialization in Fermentation and Bioprocessing. The department is accredited by Life Sciences Sector Skill Development Council (LSSDC) for two job roles QC Biologist and Production /Manufacturing Biologist.

Leading edge research carried out in the department include genomics, proteomics, cancer biology, plant-microbe interactions, biofuels, nutritional biochemistry, molecular marker studies and stress molecular biology and plant biotechnology. Members of faculty have received various extramural researches funding from agencies such as UGC, DBT, DST, VGST, BIRAC and other funding agencies and have various publications in national and international journals to their credit.

Programme Objectives:

- To provide state-of-the-art knowledge and skills in the field of Biotechnology.
- To generate manpower trained in Biotechnology suited to meet the needs of the industry and academia.
- To train students to pursue committed research in the field of Biotechnology.
- To train students for practical oriented project work.
- To have a positive impact on human and animal health, agriculture and environment in the region.
- To have 100 % placement for all the students who take up this course.

Programme Specific Outcomes (PSOs):

A post-graduate student upon completion of the programme is expected to gain the following attributes:

PSO 1: In-depth knowledge of Biotechnology with inter-disciplinary perspective of other branches of life sciences.

PSO 2: Develop an ability to solve, analyze and interpret data generated from experiments done in project work or practical courses.

PSO 3: Competence for research and innovation in Biotechnology as a skilled experimentalist.

PSO 4: Analytical and problem-solving skills with regard to biochemical principles of life processes and technologies for combating human diseases.

PSO 5: Critical thinking about the concepts in Biotechnology and ability to critically review scientific literature for development of new theories and testable hypothesis.

PSO 6: Capacity for decision making with regard to scientific progress, personal development and career choice.

PSO 7: Ability to work independently, while still promoting team work and collaboration skills.

PSO 8: Oratory (public speaking), scientific conversation and writing skills.

PSO 9: Leadership and organizational skills.

PSO 10: Execute their professional roles in society as biotechnology professionals, employers and employees in various industries, regulators, researchers, educators and managers.

PSO 11: Demonstration of integrity, honesty, ethical behaviour and sense of responsibility.

PSO 12: Appreciation of diversity in scientific community and responsibility towards society and nation.

PSO13: Environmental awareness vis-à-vis bio-waste generation, disposal and management and safety and security issues.

Course Delivery Methods

CD 1: Instructor-led Training by using chalk and board /LCD projectors/OHP projectors / group discussions.

CD 2: E-learning using LMS portal to create and integrate course materials, assessments, customized tests and virtual labs.

CD 3: Assignments/Seminars/ research paper presentation/ Review of literature

CD 4: Laboratory experiments/ hands on trainings / teaching aids.

CD 5: Industrial / guest Talks/ Webinars/workshop/conferences.

CD 6: Student Research project/ internship.

CD 7: Self- learning through various online courses including MOOCs, NPTEL, Coursera and EDX.

**DEPARTMENT OF PG STUDIES AND RESEARCH IN
BIOTECHNOLOGY CHOICE BASED CREDIT
SYSTEM (CBCS)**

Scheme and Syllabus for M.Sc. Biotechnology 2021-22 FIRST SEMESTER

Course Code	Course Title	Teaching hours per week	Credits	Duration of exam In hours	Marks		Total
					Internal Assessment	End sem. Exam	
HARD CORE COURSES – THEORY							
PH 501.1	Biochemistry and Metabolism	4	4	3	30	70	100
PH 502.1	Microbiology	4	4	3	30	70	100
PH 503.1	Cell and Molecular Biology	4	4	3	30	70	100
HARD CORE COURSES- PRACTICAL							
PH 504.1 P	Biochemistry and Metabolism	4	2	4	15	35	50
PH 505.1 P	Microbiology	4	2	4	15	35	50
PH 506.1 P	Cell and Molecular Biology	4	2	4	15	35	50
SOFT CORE COURSES – THEORY (CHOOSE ANY ONE)							
PS 507.1	Molecular and Human Genetics	3	3	3	30	70	100
PS 508.1	Immunology						
PS 509.1	Developmental Biology						
SOFT CORE COURSES PRACTICAL							
PS 510.1 P	Molecular and Human Genetics	4	2	4	15	35	50
PS 511.1 P	Immunology						
PS 512.1 P	Developmental Biology						
Total			23				600

SECOND SEMESTER

Course Code	Course Title	Teaching hours per week	Credits	Duration of exam In hours	Marks		Total
					Internal Assessment	End sem. Exam	
HARD CORE COURSES – THEORY							
PH 501.2	Genetic Engineering	4	4	3	30	70	100
PH 502.2	Enzymology	4	4	3	30	70	100
HARD CORE COURSES- PRACTICAL							
PH 503.2 P	Genetic Engineering	4	2	4	15	35	50
PH 504.2 P	Enzymology	4	2	4	15	35	50
SOFT CORE COURSES – THEORY (CHOOSE ANY TWO)							
PS 505.2	Research Methodology, Ethics and Scientific Communication	3	3	3	30	70	100
PS 506.2	Analytical Techniques in Biotechnology	3	3	3	30	70	100
PS 507.2	Multiomics						
PS 508.2	Biosafety and Bioethics						
SOFT CORE COURSES PRACTICAL							
PS 509.2 P	Research Methodology, Ethics and Scientific Communication	4	2	4	15	35	50
PS 510.2 P	Analytical Techniques in Biotechnology	4	2	4	15	35	50
PS 511.2 P	Multiomics						
PS 512.2 P	Biosafety and Bioethics						
OPEN ELECTIVES							
PO 513.2	Quality Assurance and Quality Control in Product Development	3	3	3	30	70	100
PO 514.2	Recent Trends in Biotechnology						
Total			25				700

THIRD SEMESTER

Course Code	Course Title	Teaching hours per week	Credits	Duration of exam In hours	Marks		Total
					Internal Assessment	End sem. Exam	
HARD CORE COURSES – THEORY							
PH 501.3	Animal Biotechnology	4	4	3	30	70	100
PH 502.3	Plant Biotechnology	4	4	3	30	70	100
HARD CORE COURSES- PRACTICAL							
PH 503.3 P	Animal Biotechnology	4	2	4	15	35	50
PH 504.3 P	Plant Biotechnology	4	2	4	15	35	50
SOFT CORE COURSES – THEORY (CHOOSE ANY TWO)							
PS 505.3	Industrial Biotechnology	3	3	3	30	70	100
PS 506.3	Environmental Biotechnology	3	3	3	30	70	100
PS 507.3	Plant Breeding and Seed Technology						
PS 508.3	Marine Biotechnology						
SOFT CORE COURSES PRACTICAL							
PS 509.3 P	Industrial Biotechnology	4	2	4	15	35	50
PS 510.3 P	Environmental Biotechnology	4	2	4	15	35	50
PS 511.3 P	Plant Breeding and Seed Technology						
PS 512.3 P	Marine Biotechnology						
OPEN ELECTIVES							
PO 513.3	Clinical Drug Development and IPR	3	3	3	30	70	100
PO 514.3	Bioremediation techniques						
Total			25				700

FOURTH SEMESTER

Course Code	Course Title	Teachin g hours per week	Credits	Duration of exam In hours	Marks		Total
					Internal Assessment	End sem. Exam	
HARD CORE COURSES – THEORY							
PH 501.4	Food Biotechnology	4	4	3	30	70	100
PH 502.4	Molecular Diagnostics and Immunotechniques	4	4	3	30	70	100
PH 503.4	Project Dissertation/ Internship Repost and Viva Voce	8	4	Dissertation and Viva Voce	30	70	100
HARD CORE COURSES- PRACTICAL							
PH 504.4 P	Food Biotechnology	4	2	4	15	35	50
PH 505.4 P	Molecular Diagnostics and Immunotechniques	4	2	4	15	35	50
SOFT CORE COURSES – THEORY (CHOOSE ANY ONE)							
PS 506.4	Clinical Research, IPR and Patents	3	3	3	30	70	100
PS 507.4	Stem Cell Technology and Regenerative Medicine						
PS 508.4	Bio- entrepreneurship						
Total			19				500

Total Marks = 2500 and Total credits = 92

Semester	Hard core courses			Soft core courses			Open Electives	Project	Total
	No of courses	Credits	Total	No of courses	Credits	Total	Credits	Credits	
I	3T+3P	12+6	18	1T+1P	3+2	5	-	-	23
II	2T+2P	8+4	12	2T+2P	6+4	10	3	-	25
III	2T+2P	8+4	12	2T+2P	6+4	10	3	-	25
IV	2T+2P	8+4	12	1T	3	3	-	4*	19
Total			52+4 = 60.87 %			30 = 32.61 %	6 = 6.52%		92

*** Project considered as hard core**

SEMESTER – I

PH 501.1 BIOCHEMISTRY AND METABOLISM

Hours: 56

Course Objectives:

This course enables the students to:

- Appreciate the structure and functions of carbohydrate, protein, lipid and nucleic acid.
- Understand how the structure of biological molecules dictates its function.
- Extend comprehensive knowledge about biochemical pathways involved in intermediary metabolism of carbohydrate, protein, lipid and nucleic acid.
- Interrelate each of the metabolic pathways and their contributions in various metabolic disorders.

Course Outcomes:

At the end of the course, a student should be able to:

- Delineate structure, function and interrelationships of various biomolecules and consequences of deviation from the normal.
- Translate the importance of biological macromolecules and their role in living systems.
- Execute a particular metabolic pathway involved in carbohydrate, lipid, amino acid and nucleic acid metabolism, their interconnections.
- Evaluate information relevant to concepts on cellular regulation of different metabolic pathways.

UNIT I

(14 hrs)

Structural biology of carbohydrates and lipids

Glycobiology: Monosachharides- classification, structure and isomerism in monosaccharides (stereoisomers, Epimers, Anomerism and Mutarotation).

Disaccharides - Glycosidic bond, structure and functions of sucrose, lactose and maltose. Polysaccharides- Structure and functions of starch and glycogen. Glycosaminoglycans- structure and functions of Hyluronate.

Lipids: Classification- structure and properties of – phospholipids, glycolipids, and sphingolipids. Classification- Fatty acids – short chain, medium chain and long chain; saturated and unsaturated. Triglycerides, structure and properties of lipoproteins- HDL, LDL, VLDL.

UNIT II

(14hrs)

Structural biology of amino acids, proteins & nucleic acids

Amino acids: Classification based on charge and polarity, essential, non-essential amino acids, ketogenic and glucogenic amino acids, non-protein amino acids.

Proteins: peptide bond, Conformation of proteins: Ramachandran plot, hierarchy in structure - primary, secondary, tertiary and quaternary with suitable examples - hemoglobin; domains; motif and folds., End group analysis and sequencing.

Nucleic acids: Conformation of helix (A, B, Z), Chargaff's rule, properties of DNA - denaturation, renaturation, melting temperature, hyperchromicity, cot curve, structure of t-RNA and miRNA.

UNIT III

(14 hrs)

Metabolism of carbohydrates

Glycolysis and its regulation, Cori's cycle, Gluconeogenesis, regulation of blood sugar, TCA cycle and its regulation, Mitochondrial Electron Transport chain: structural components of the chain, complexes, free elements; Chemiosmosis ATP synthesis, Inhibitors of ETC and ATP synthesis, Pentose phosphate pathway & its regulation.

UNIT IV

(14 hrs)

Metabolism of lipids, amino acid & nucleic acid

Amino acid metabolism: Biodegradation of amino acids – deamination, transamination, decarboxylation, urea cycle and its regulations.

Nucleic acids: *De novo* and Salvage pathways of purine and pyrimidine ribonucleotides and its regulation.

Lipid metabolism: Lipid metabolism: Synthesis of lipids, β -oxidation of saturated (palmitic acid) and unsaturated (oleic acid) fatty acids and energetics. Cholesterol biosynthesis (scheme), Ketone body metabolism – Ketogenesis and Ketolysis.

REFERENCES:

1. Garret, R. H., & Grisham, C. M. (2012). Biochemistry, 4th ed., Massachusetts: Mary Finch Publishers.
2. Jain, J. L., Sunjay, J., & Nithin, J. (2012). Fundamentals of Biochemistry, 6th ed., New Delhi: S. Chand & Company.

3. Koolman, J., & Roehm, K. H. (2013). Color Atlas of Biochemistry, 3rd ed., New York: Thieme Medical Publishers.
4. Lehninger, A. L. (2012). Principles of Biochemistry, 6th ed., New York: Macmillan Learning.
5. Murray, R. K., Granner, D. K., Mayer, P. A., & Rodwell, V. W. (2009). Harper's Biochemistry, 28th ed., Connecticut: Appleton & Lange.
6. Puri, D. (2011). Textbook of Medical Biochemistry, 3rd ed., India: Elsevier.
7. Satyanarayan, U., & Chakrapani, U. (2019). Biochemistry, 5th ed., Kolkata: Books and Allied (P) Ltd.
8. Stryer, L. (2015). Biochemistry, 8th ed., New York: Freeman Publishers.
9. Voet, D., & Voet, J. G. (2016). Biochemistry, 5th ed., Hoboken, New Jersey: J. Wiley & Sons.
10. White, A., Handler, P., & Smith, E. L., (2004). Principles of Biochemistry, 6th ed., New Delhi: Tata McGraw Hill.

Course objectives:

This course enables the students to:

- Understand the diversity in microbial world and the concept of microbial taxonomy and phylogeny.
- Describe the mechanisms of various interactions that exist between the microbes, microbes and higher forms of life/environment.
- Distinguish principles of virus taxonomy, structure, life cycle, and host-virus interactions that often lead to disease.
- Appraise the applications of relevant microbes in agriculture, healthcare and environment.

Course Outcomes:

At the end of the course, a student should be able to:

- Apply the principles in classifying microbial systems and know their beneficial and harmful effects.
- Employ various cultivation methods starting from screening to preservation of the desired microbe.
- Understand the major virus groups with their elementary features that is responsible for causing the most dreaded diseases.
- Appreciate the microbial diversity and their interactions, and design suitable strategies to tackle unsustainable agricultural and environmental practices.

UNIT I**(14 hrs)****Introduction to Microbiology and Systematics**

Isolation and cultivation of microorganism: Nutritional types of bacteria; Culture media types (Complex, synthetic, differential, enrichment and selective media) and their uses; Pure culture techniques; Maintenance and preservation of microbial culture. Culture Collection Centers.

Microbial growth: Bacterial growth curve; Batch, continuous and synchronous culture; Measurement of microbial growth; Environmental effects on growth (Temperature, pH, osmolarity and oxygen); Aerobic and anaerobic culture.

Microbial Taxonomy and Omics: Phylogenetic classification; Genetic classification; Numerical taxonomy; Molecular identification methods (Nucleic acid base composition,

nucleic acid hybridization, nucleic acid sequencing, genome fingerprinting, amino acid sequencing); Assessing microbial phylogeny (Phylogenetic trees). 16S rDNA sequencing; Ribosomal Database Project; Metagenomics.

UNIT II

(14 hrs)

Microbial symbiosis and microbiome

General account of symbiosis in microorganisms: Mutualism, antagonism, parasitism, commensalism

Plants as microbial habitats: Mycorrhizae and its types; Legume-root nodule symbiosis

Microbiome: Human microbiome and its significance; Microbiomes of Extreme Environments: Properties and adaptation of extremophiles (Hyperthermophiles, psychrophiles, halophiles, acidophiles and alkaliphiles).

UNIT III

(14 hrs)

Morphology and Pathogenesis of Viruses

Viruses and their replication: Classification (General and Baltimore); Ultra-structure, Viroids and Prions; Viral replication: Life cycle (Lytic and lysogenic cycles); Isolation and cultivation of viruses in embryonated eggs, experimental animals, and cell cultures.

Assay of viruses: Physical and chemical methods (Protein, nucleic acid, electron microscopy). Infective assay (Plaque method, end point method).

Host- Pathogen interaction: Plant viruses (TMV and Gemini virus); Animal viruses (HIV, H1N1 and SARS); Bacteriophages: T4 lambda phage - Decision between lysis and lysogeny.

UNIT IV

(14 hrs)

Economic importance of microorganisms

Agricultural Microbiology: Mass production and field applications of Ectomycorrhizae and VAM, Azolla- anabaena. Isolation, characterization, mass production, field application and assessment of Rhizobium, Azotobacter. Phosphate Solubilizing Microorganisms (PSM); Integrated Pest Management (Biopesticides: *Bacillus thuringiensis*).

Environmental Microbiology: Microbial fuel cells- hydrogen production. Production of bioplastics (PHB, PHA).

Pharmaceutical Microbiology: Importance of extremophilic microbial diversity in pharmaceuticals & human health industry. Marine microorganisms and drug discovery:

Bioactive compounds as antibacterial, antiviral, antifungal and antitumor agents. Quorum sensing and antimicrobial therapy.

REFERENCES:

1. Black, J. G., & Black, L. J. (2017). Microbiology: Principles and Explorations, 10th ed., United States of America: John Wiley & sons, Inc.
2. Cann, A. J. (2016). Principles of Molecular Virology, 6th ed., London: Academic Press.
3. Dimmock, N. J., Easton, A. J., & Leppard, K. N. (2016). Introduction to Modern Virology, 7th ed., United Kingdom: Wiley-Blackwell.
4. Flint, J., Racaniello, V. R., Rall, G. F., & Skalka, A. M. (2015). Principles of Virology, 4th ed., Washington DC: ASM Press.
5. Madigan, M. T., Bender, K. S., Buckley, D. H., Sattley, W. M., & Stahl, D. A. (2019). Brock Biology of Microorganisms, 15th ed., Harlow, United Kingdom: Pearson.
6. Pommerville, J. C. (2011). Alcamo's Fundamentals of Microbiology, 9th ed., Sudbury, Massachusetts: Jones and Bartlett Publishers.
7. Sullia, S. B., & Shantharam, S. (2005). General Microbiology, 2nd ed., New Delhi: Oxford & IBH Publishing Co. Pvt. Ltd.
8. Talaro, K. P. (2009). Foundations in Microbiology: Basic Principles, 7th ed., New York: McGraw-Hill.
9. Tortora, G. J., Funke, B. R., & Case, C. L. (2015). Microbiology: An Introduction, 12th ed., United States of America: Pearson Education Inc.
10. Willey, J. M., Sherwood, L. M., & Woolverton, C. J. (2016). Prescott, Harley, and Klein's microbiology, 10th ed., Americas, New York: McGraw-Hill.

Course Objectives:

This course enables the students to:

- Understand molecular organization of membranes and membrane functions.
- Appreciate cellular processes and cell signaling.
- Understand the flow of information from genes to proteins.
- Comprehend cell transformation mechanisms.

Course Outcomes:

At the end of the course, a student should be able to:

- Describe the organization of macromolecules on membranes and cellular processes.
- Differentiate the various cell signaling pathways.
- Illustrate regulation of gene expression in eukaryotes.
- Take up research in the field of cell and molecular biology.

Unit I**(14 hours)****Organization of biological membranes and cellular processes**

Physicochemical properties of biological membranes – compositions, molecular organization, Transport across bio membranes - Active and Passive transport. Molecular mechanisms of nuclear transport, transport across mitochondria and chloroplasts, intracellular vesicular trafficking. Electrical properties of membranes.

Cell cycle and its regulation, cell-extra cellular matrix and cell-cell interactions, cell receptors (cell surface receptors and nuclear receptors) and signalling. Cell death pathways and their regulation.

Unit II I**(14 hours)****Flow of genetic information in Eukaryotic systems**

Eukaryotic DNA replication: Enzymology and control of DNA replication. Eukaryotic Transcription-initiation, elongation and termination. Promoters, enhancers, transcription factors, RNA processing, modification in RNA: 5'-Cap formation; 3'-end processing and polyadenylation, RNA splicing in rRNA, tRNA and mRNA. Translation in Eukaryotes:

initiation of translation, chain elongation, termination of protein synthesis, post-translational modification and protein splicing.

Unit III

(14 hours)

Regulation of Gene expression in Eukaryotes

Regulation at the level of genome-DNA amplification, DNA rearrangement, Chromatin remodelling and DNA methylation. Transcriptional control of gene expression- -various protein motifs involved in DNA protein interaction during transcription, Hormones (steroid and peptide hormones) and Environmental factors (hypoxia, infection, stress) affecting gene expression. Post-transcriptional regulation: Alternative splicing and Trans-splicing, RNA Editing, Translational and Post translational control. Genetic basis of differentiation-molecular aspects of pattern formation in *Drosophila*; Role of maternal effect genes, gap genes, pair rule genes, segment polarity genes and homeotic selector genes in anterior-posterior axis formation. Role of dorsal protein in specifying the dorso-ventral axis.

Unit IV I

(14 hours)

Molecular basis of cell transformation and therapy

Cancer: Causes of Cancer, Types of cancer, differences between normal and cancer cells. Mechanism of transformation of cells, metastasis.

Genetic basis of Cancer: Cellular oncogenes - Oncogene families: Protein kinases (*Src*, *ablr*, *bbl*), GTP binding proteins (*H-ras*, *K-ras*), growth factors (*sis*), nuclear proteins (*myc*, *myb*, *fos*), hormone receptors (*erbA*) and unclassified. Protooncogenes- activation to oncogenes, and Retroviral oncogenes (*v-src*, *v-sis*, *v-erbA* or *v-erbB*, *v-kras*, *v-mos*, *v-myc*). Tumor suppressor genes-their role in cell cycle control and tumor development (RB, p16, p21, PTEN).

Cancer therapy: Chemotherapy, Radiotherapy, Immunotherapy.

REFERENCES:

1. Alberts, B., Hopkin, K., Johnson, A., Morgan, D., Lewis J., Raff M., Roberts, K., & Walter, P., (2019). Essential Cell Biology, International student edition, 5th ed., New York: W. W. Norton & Co.
2. Baressi, M. J. F., & Gilbert, S. F., (2019). Developmental Biology, 12th ed., Massachusetts: Sinauer Associates.

3. Brooker, R. J. (2017). Genetic analysis and principle, 6th ed., New York: McGraw Hill Education.
4. Brown, T. A., (2017). Genomes 4, New York: Garland Science, Taylor and Francis group.
5. Cooper, G. M., & Sinauer G.M., (2019). The Cell: A Molecular Approach, International 8th ed., United Kingdom: Oxford University Press.
6. Hardin, J. & Bertoni, G. P. (2018). Becker's World of The Cell, 9th ed., USA: Pearson Education Ltd.
7. Karp, G., Iwasa, J., & Marshall W. (2016). Cell and Molecular Biology: Concepts and Experiments, 8th ed., New York: Wiley & sons.
8. Krebs, J. E., Goldstein, E. S., & Kilpartick, S. T. (2017). Lewin genes- XII, Burlington: Jones and Bartlett Publishers.
9. Lodish, H., Berk, A., Kaiser, C. A., Krieger, M., Bretscher, A., Ploegh, H., Amon, A., & Martin, K., (2016). Molecular Cell Biology, 8th ed., New York: W. H. Freeman & Co.
10. Tropp, B. E. (2020). Molecular Biology: Genes to Proteins, 5th ed., New York: Jones & Bartlett Learning.

Course Objectives:

This course enables the students to:

- Appreciate various quantitative analysis of the macromolecules in the given sample and analyse the results.
- Learn the preparation of buffers, reagents, standard solutions for various methods of estimation of proteins, carbohydrates and lipids.
- Provide a deep insight of the various methods and techniques used in microbial isolation, staining, enumeration and preservation.
- Apply standard methods and techniques in biochemistry with the appropriate analysis and interpretation of data and results.

Course Outcomes:

At the end of the course, a student should be able to:

- Apply knowledge of biochemistry and metabolism in various cellular functions, and the application of research involved in various biochemical processes.
- Investigate and analyse the unknown carbohydrate or amino acid compound present in the given sample qualitatively.
- Demonstrate a proficiency in developing relevant biochemical questions, carrying out laboratory investigations to answer those questions, and critically analysing, interpreting, and presenting the results of their experiments.
- Construct the standard curve, analyse the data and interpret the results.

List of Practicals:

1. Laboratory safety and guidelines.
2. Preparation of buffers and solutions.
3. Qualitative analysis of carbohydrates.
4. Qualitative test for amino acids.
5. Estimation of proteins by Lowry's method.
6. Estimation of Glucose by anthrone method.
7. Determination of Fructose by Resorcinol Method.
8. Estimation of total carbohydrates by phenol sulphuric acid method.
9. Determination of Saponification Value of Fats and Oils.
10. Determination of iodine value of oil.

Course Objectives:

This course enables the students to:

- Understand and appreciate the laboratory safety protocols.
- Examine the presence and central roles of microorganisms in nature and in our daily lives.
- Become adept with microbiological techniques to isolate, investigate the structure and physiology, identify and preserve the isolated microorganism.
- Become proficient in laboratory skills and critical thought required to implement the skills.

Course Outcome:

At the end of the course, a student should be able to:

- Evaluate the various physical and chemical growth requirements of bacteria and equip various methods of bacterial growth measurement.
- Execute microbial techniques for the isolation of pure cultures of bacteria.
- Master staining procedures, aseptic techniques and be able to perform routine culture handling tasks safely and effectively.
- Comprehend the various methods for identification of unknown microorganisms.

List of Practicals:

1. ***Survey of microorganisms:*** Ubiquity of Bacteria.
2. ***Manipulation of microorganisms:*** Pure culture techniques (Streak-plate, pour-plate, and sub-culturing techniques).
3. ***Enumeration of bacteria:*** Standard plate count; Determination of growth by absorbance (Optical density).
4. ***Preservation and maintenance of microorganisms:*** Stock culture; Sub-culture; Cold storage; Oil storage.
5. ***Staining and observation of microorganisms:***
Staining: Simple staining; Negative staining; Capsular staining; Gram staining; Spore staining; Viability test using Fluorescent stains.
Motility determination: Hanging drop slides; Tube method.
6. ***Identification of unknown microorganism:***

Culture characteristics: Growth on nutrient-agar slants; Growth in nutrient broth; Growth on nutrient- agar plate (Configuration, margin, elevation).

Physiological characteristics:

- Oxidation test (Oxidase, catalase test).
- Fermentation tests (O/F glucose; Specific sugar fermentations)
- Hydrolytic and degradation test (Starch hydrolysis, Tryptophan hydrolysis, Urea hydrolysis).
- Multiple Test Media (IMViC Test).

7. ***Environmental factors affecting the growth:*** Temperature; pH

8. **Use of Bergey's Manual:** Classification of bacteria and Archaea according to the Bergey's Manual of Systematic Bacteriology.

Course Objectives:

This course enables the students to:

- Have hands-on-training in cell and molecular biology techniques.
- Calculate and prepare reagents.
- Comprehend the underlying principle of quantitative and qualitative experiments.
- Identify suitable model organisms to perform experiments.

Student Learning Outcomes:

At the end of the course, a student should be able to:

- Assess membrane transport.
- Prepare slides.
- Differentiate cell divisions.
- Isolate macromolecules and perform qualitative and quantitative assays.

List of Practicals:

1. Study of plasmolysis in cells of *Rheo* leaves.
2. Determination of mitotic index in onion root tips.
3. Study of meiosis in Onion inflorescence/grasshopper testis- determination of frequency of chiasma.
4. Dissection and mounting of imaginal discs.
5. Isolation of genomic DNA.
6. Purification of extracted DNA.
7. Characterization of purified DNA (purity and T_m).
8. Estimation of DNA by diphenylamine method.
9. Isolation of RNA from coconut endosperm.
10. Estimation of RNA by orcinol method.

Course Objectives:

This course enables the students to:

- Understand the classical concepts of Mendelian genetics, gene interactions and the repair mechanisms.
- Categorize the genetic recombination in bacteria and inspect the molecular mechanism of recombination.
- Acquire a deep insight on some of the chromosomal abnormalities and their diagnosis.
- Comprehend the concepts of population genetics, the theories and genetics of evolution.

Course Outcomes:

On completion of this course, a student should be able to:

- Discuss the chromosomal mechanisms of sex determination and dosage compensation.
- Demonstrate the ability to distinguish between a normal and an abnormal karyotype and the underlying causes of genetic disorders at the molecular level.
- Categorize the different methods available for genetic testing and for the treatment and management of genetic disorders.
- Construct pedigrees and analyse the patterns of inheritance in the families.

UNIT I**(16 hrs)**

Mendelian genetics: Multiple alleles, Interaction of genes.

Non-Mendelian genetics: Sex determination, Dosage compensation.

Plasmids and Gene transfer in bacteria: Biology of Plasmids, Transformation, Transduction: Specialized and generalized, Conjugation – F and Hfr.

Mutagenesis & DNA repair: *In vitro* mutagenesis: Oligonucleotide directed mutagenesis. Types of DNA damage and DNA repair mechanisms-photo-reactivation, base and nucleotide excision, mismatch, recombination, SOS.

Homologous recombination: Holliday model, Site specific recombination.

UNIT II

(16 hrs)

Human genetics

Pedigrees-gathering family history, pedigree symbols, construction of pedigrees, Human karyotype construction, Common syndromes due to numerical chromosome changes with eg. monosomy: Cri-du-chat, trisomy: Down's, Patau, Edwards. Structural alterations - Deletions, microdeletion: Angelman and Prader-Willi, fragile sites: Martin-Bell syndrome, Duplications: Isodicentric 15; Translocations: Reciprocal - Familial Down's, Non reciprocal-Robertsonian. Laboratory diagnosis of genetic disorders: Prenatal diagnosis (amniocentesis and chorionic villus sampling), inborn errors of metabolism by mass spectrometry based diagnosis, Liquid biopsy. Genetic Counselling.

Human genome project: Concept, goals and objectives, initiation, phases, contents, implications and benefits.

UNIT III

(16 hrs)

Evolutionary genetics

Theories of origin of life-Special creation, Catastrophism, Panspermia, Abiogenesis, Biogenesis (experiments of Francesco Redi, Spallanzani and Pasteur), Biochemical origin of life – Chemogeny (origin of organic and inorganic compounds, coacervates and microspheres). Organic evolution: Lamarckism, Darwinism, Neo Darwinism, De Vries Mutation Theory, Recapitulation Theory.

Population genetics – Allele frequencies, Hardy-Weinberg equilibrium and conditions for its maintenance. Speciation- Sympatric, allopatric.

REFERENCES:

1. Brooker, R. J., (2017). Genetic analysis and principle, 6th ed., New York: McGraw Hill Education.
2. Dale, J. W. (2010). Molecular genetics of Bacteria, 5th ed., United States: John Wiley and Sons.
3. Hartl, D. L. (2018). Essential genetics: A genomics perspective, 7th ed., Boston: Jones & Bartlett.
4. Hartl, D. L., & Ruvolo, M. (2012). Genetics: Analysis of genes and genomes, 8th ed., Boston: Jones & Bartlett.
5. Knustad, D. P., & Simmons M. J. (2015). Principle of genetics- 7th ed., United States: John Wiley and Sons.

6. Krebs, J. E., Goldstein, E. S., & Kilpartick, S. T. (2017). *Lewin genes- XII*, Burlington: Jones & Bartlett Publishers.
7. Maloy, S. R., Cronan, J. E., & Friefelder, D. (2013). *Microbial genetics*, 2nd ed., United States: Jones & Bartlett.
8. Read, A., & Donnai, D. (2015). *New Clinical genetics*, 3rd ed., United Kingdom: Scion Publishing Ltd.
9. Tamarin, R. (2017). *Principles of Genetics*, 7th ed., New York: McGraw Hill Education.
10. Watson, J. D., Baker, T. A., Bell, S. P., Gann, A. I., Levine, M. L., & Losick, R. (2017). *Molecular Biology of gene*. 7th ed., San Francisco: Pearson Education.

Course Objectives:

This course enables the students to:

- Provide an insight into various organs and cell types involved in immune responses and associated functions.
- Compare and contrast the innate versus adaptive immune systems.
- Distinguish and characterize antibody isotypes, development, functions and antigen-antibody reactions.
- Provide students with knowledge on how the immune system works during bacterial infection and viral infections.

Course Outcomes:

At the end of the course, a student should be able to:

- Describe which cell types and organs present in the immune response.
- Apply basic techniques for identifying antigen-antibody interactions.
- Exemplify the adverse effect of immune system including allergy, hypersensitivity and autoimmunity.
- Elucidate the reasons for immunization and aware of different vaccination.

UNIT I**(14 hrs)**

Types of immunity: Innate and adaptive immunity, Cells and organs of the immune system. Antigens and haptens/incomplete antigens, adjuvants. Immunoglobulins: structure and function. Receptors on T and B cells. Antigenic determinants. Antigen-antibody reactions: Agglutination, Precipitation, immunodiffusion. Affinity and avidity.

UNIT II**(14hrs)**

Organization and Expression of Immunoglobulin Genes: Antibody diversity-V (D) J rearrangements; somatic hypermutation and affinity maturation. Major Histocompatibility Complex. Antigen processing and presentation: endogenous and exogenous pathways. B-cell: Activation, maturation and differentiation. T-cell: activation, maturation and differentiation.

UNIT III**(14 hrs)**

Effector mechanisms in immunity: cytokines, cytokine antagonists, complement system-complement activation and pathways. Hypersensitivity reactions: Types I, type II, type III & type IV. Immune response to infectious diseases: bacterial (tuberculosis), parasitic (malaria) and viral (AIDS, COVID). Autoimmune diseases: Rheumatoid Arthritis. Vaccines.

REFERENCES:

1. Abbas, A., Lichtman, A. H., & Pillai, S., (2017). Cellular and Molecular Immunology, 9th ed., Philadelphia: Elsevier.
2. Coico, R., & Sunshine, G., (2015). Immunology: A Short Course, 7th ed., United Kingdom: John Wiley & Sons Ltd.
3. Delves, P. J., Martin, S. J., Burton, D. R., & Roitt, I. M. (2017). Roitt's Essential Immunology, 13th ed., United Kingdom: John Wiley & Sons Ltd.
4. Goering, R., Dockrell, H., Zuckerman, M., & Chiodini, P. (2018). Mims Medical Microbiology and Immunology, 6th ed., Elsevier Ltd.
5. Paul, W. E. (2014). Fundamental Immunology, 7th ed., Philadelphia: Lippincott Williams & Wilkins.
6. Male, D., Brostoff, J., Roth, D. B., & Roitt, I. V. (2012). Immunology, 8th ed. Elsevier Saunders.
7. Murphy, K. & Weaver, C. (2016). Janeway's Immunobiology, 9th ed., New York: Garland Science.
8. Playfair, J. H. L., & Chain, B. M. (2012). Immunology at a Glance, 10th ed., United States: Wiley-Blackwell.
9. Punt, J., Stranford, S., Jones, P., & Owen, J.A. (2019). Kuby Immunology, 8th ed., United States: Macmillan Learning.
10. Tizard, I. R. (2000). Immunology: An Introduction, 4th ed., India: Ceneage Learning.

Course objectives

This course enables the students to:

- Acquaint with the physiology of reproduction in chordates.
- Learn the molecular and cellular mechanisms that underlie the early development of organisms.
- Understand the key steps in the transformation of the single-celled zygote into the complex, multicellular, adult organism.
- Comprehend how the genes play a role in axis specification and embryogenesis.

Course Outcomes:

At the end of the course, a student should be able to:

- Describe the main stages of development common to most multicellular organisms.
- Demonstrate the cellular behaviours that lead to morphological change during development.
- Illustrate how gene activation plays a role in differentiation.
- Apply the knowledge gained in the field of research.

UNIT I**(14 hrs)****Historical perspectives, Gametogenesis and Fertilization:**

Introduction: Definition, scope & historical perspective of development Biology.

Gametogenesis: Spermatogenesis, Oogenesis; Fertilization: Concept and types, molecular events during fertilization - capacitation of sperm, recognition of sperm and egg, acrosome reaction, activation of egg, fusion of egg and sperm cell membrane; Species specific recognition of gametes – fertilizin and antifertilizin interaction, binding protein, prevention of polyspermy – Fast and slow block, calcium as initiator of cortical granule reaction, activation of egg metabolism.

UNIT II:**(14 hrs)****Post fertilization events and Early embryonic development:**

Cleavage: Definition, types, patterns & mechanism; Blastulation: Process, types & mechanism; Gastrulation: Morphogenetic movements– epiboly, emboly, extension,

invagination, convergence, de-lamination. Formation & differentiation of primary germ layers, Fate Maps in early embryos.

UNIT III:

Embryonic Differentiation and Organogenesis: (14 hrs)

Differentiation: Mechanisms- cytoplasmic determinants, concept of embryonic induction - Primary, secondary & tertiary, Neurulation, notogenesis, Fate of different primary germ layers.; Body axes –establishment of body axis in mammals; Homeobox concept – homeotic genes.

REFERENCES:

1. Balinsky, B. I. (2008). An introduction to Embryology, Japan: Toppan Company Limited
2. Davidson, E. H., & Levine, M. (2005). Gene activity in Early Development, 3rd ed., New York: Academic Press, Inc.
3. Gilbert, S. F., & Singer, S. R. (2006). Developmental Biology, 8th ed., Massachusetts: Sinauer Associates Inc.
4. Kalthoff (2000). Analysis of Biological Development, 2nd ed., New York: McGraw-Hill Professional.
5. Slack, J. M. W. (2012). Essential Developmental Biology, 3rd ed., United Kingdom: Wiley Blackwell Publishers.
6. Subramoniam, T. (2011). Molecular developmental biology, 2nd ed., United Kingdom: Alpha Science International Ltd.
7. Sussman, M. (2011). Animal growth and development, United States: Prentice Hall.
8. Twyman, R. M. (2001). Developmental Biology, 1st ed., Taylor and Francis.
9. Wilt, F. H., & Hake, S. C. (2003). Principles of Developmental Biology. 1st ed., New York: W. W. Norton & Company.
10. Wolpert, L. (2011). Developmental Biology: A Very Short Introduction, 1st ed., United Kingdom: Oxford University Press.

Course Objectives:

This course enables the students to:

- Acquire the required laboratory skills to perform, interpret and analyze the results.
- Demonstrate the handling of *Drosophila melanogaster*, the model organism for genetic studies.
- Describe the principles and procedures of genetic techniques in biological experiments.
- Perform and elucidate the reasons for the given karyotype.

Course Outcome:

At the end of the course, a student should be able to:

- Describe the salient features of *Drosophila melanogaster*.
- Apply the basic technique of separation of the eye pigments of *D. melanogaster* by chromatographic technique.
- Analyze the different types of syndrome and their karyotype.
- Elaborate the knowledge on sex determination and chromosomal aberrations.

List of Practicals:

1. Salient features of *Drosophila melanogaster*.
2. Mounting of sex comb of *Drosophila*.
3. Study of mutant forms of *Drosophila*.
4. Chromatographic separation of eye pigments in *Drosophila*.
5. Polytene chromosome from salivary glands of *Drosophila melanogaster*.
6. Study of chromosomal aberrations in onion root tip.
7. Study of Barr Body from human buccal epithelial cells.
8. Human karyotyping.
9. Problems in population genetics.
10. Antibiotic resistance by gradient plate technique.

Course Objectives:

This course enables the students to acquire adequate skills and knowledge to:

- Stain and identify different cells of immune system.
- Perform agglutination and precipitation reactions.
- Identify blood groups and types.
- Visit blood bank to understand the blood donation, packing, separation of blood products.

Course Outcome:

At the end of the course, a student should be able to:

- Acquire technical skills and knowledge on staining, identify various immune cells and enumerate them.
- Competently perform antigen-antibody interaction for diagnostic test.
- Analyze the components of human sera by performing agarose gel electrophoresis.
- Perform blood Donation and its procedure, product packing, separation of blood products and labeling.

List of Practicals:

1. Whole count of WBCs.
2. Differential count of WBCs.
3. Latex Agglutination reactions.
4. Heamagglutination Reactions-blood grouping.
5. Serum electrophoresis.
6. Coomb's test.
7. Ouchterlony Immunodiffusion.
8. Radial Immunodiffusion.
9. Isolation of lymphocytes from peripheral blood.
10. Visit to blood bank.

Course Objectives:

This course enables the students to:

- Understand the structural organization and early development of organisms.
- Gain in-depth knowledge about the transformation of the single-celled zygote into the complex, multicellular, adult organism.
- Have expertise in various skilled techniques.
- Prepare various types of tissues/cells for staining.

Course Outcome:

At the end of the course, a student should be able to:

- Assess the importance of model organisms in developmental biology.
- Distinguish between the stages of development of different organisms.
- Develop practical skills in isolation and staining.
- Apply the knowledge in contribution towards research.

List of Practicals:

1. Study of model organisms used in developmental biology
2. Life cycle and metamorphosis in frogs
3. Structure of chick egg
4. Study of chick embryo by vital staining technique
5. Structure of sperms few reproductive animals.
6. Developmental stages in frog
7. Developmental stages in chick.
8. Study of spermatogenesis in rat and structure of sperms in a few reproductive animals.
9. Analysis of testicular extract/ semen – Fish / Chicken / Goat
 - i. pH, Viscosity, Agglutination
 - ii. Sperm count and motility – Fish / Chicken / Goat
 - iii. Hypo-osmotic swelling of sperm – Normal / Abnormal
10. Measurement of fish ova diameter using oculometer.

Course objectives:

This course enables the students to:

- Understand the tools and techniques employed in genetic engineering.
- Describe various methods of gene transfer, selection and screening of recombinants.
- Comprehend forward and reverse primer design.
- Learn recent developments in PCR and Transcriptomic analysis.

Course Outcomes:

At the end of the course, a student should be able to:

- Demonstrate the ability to design recombinant molecules.
- Design forward and reverse primer to amplify a gene of interest.
- Explain transcriptomic analysis and major RNA-Seq platforms.
- Apply learned knowledge to their future research.

UNIT I (14 hrs)

Introduction to rDNA technology, Restriction-modification systems: Restriction enzymes-types, Isoschizomers, Double digests, Restriction mapping. DNA Ligases. Klenow enzyme, T4 DNA polymerase, Polynucleotide kinase, Alkaline phosphatase; Cohesive and blunt end ligation; Linkers; Adaptors; Homopolymeric tailing. TA cloning. Construction of libraries: genomic library; Isolation of mRNA and methods of cDNA synthesis and construction of cDNA library.

UNIT II (14 hrs)**Vectors and gene transfer techniques**

Essential features of cloning vectors and expression vectors. pUC19; pBR322, M13 mp vectors; Artificial chromosome vectors (YAC, BAC, MAC); Expression vectors; pMal; GST; pET-based vectors; Vectors for Protein purification; His-tag; GST-tag; MBP-tag.

Agrobacterium mediated gene transfer Ti plasmid, role of vir and chromosomal genes in T-DNA transfer. Agrobacterium vectors: co integrative and binary vectors and their utility.

UNIT III

(14 hrs)

Transformation, Selection and screening of recombinants

Physical and chemical methods of gene transfer: Biolistics, Microinjection, electroporation, sonoporation, Calcium phosphate co precipitation, Liposome mediated transformation, PEG, DEAE dextran.

Selectable markers: antibiotic resistant and anti-metabolite resistant markers, Insertional inactivation-blue/white selection, marker-free methodologies. colony and plaque hybridization. Screening using probes: Construction of gene probes (radioactive and nonradioactive labeling). Nucleic acid hybridization- Southern blotting.

UNIT IV

(14hrs)

PCR and analysis of gene expression

Primer design; Fidelity of thermostable enzymes; DNA polymerases; Types of PCR – multiplex, nested, reverse transcriptase, real time PCR. PCR in Site specific mutagenesis; PCR in molecular diagnostics; Viral and bacterial detection. DNA sequencing: Sanger and Coulson's method and its automation. Transcriptomic Analysis: RNA- Seq, Ribosome Profiling, Long Noncoding RNAs, Small Noncoding RNAs (miRNA-seq). Major RNA-Seq platforms-Ion torrent, Illumina, Pac Bio, MinION nanopore.

REFERENCES:

1. Biassoni, R., & Raso A. (2020). Quantitative Real-Time PCR: Methods and Protocols, 2nd ed., United States: Humana Press.
2. Brown, T. A., (2017). Genomes 4, 4th ed., Garland Science, New York: Taylor and Francis.
3. Huss, M., Korpelainen, E., Somervuo, P., Tuimala, J., & Wong, G. (2017). RNA-seq data analysis: A practical approach. United States: CRC Press.
4. Korpelainen, E., Tuimala, J., Somervuo, P., Huss M., & Wong, G. (2014). RNA-seq Data Analysis: A Practical Approach, 1st ed., United States: CRC Press Taylor & Francis Group.
5. Lewin, B. (2010). Genes, 10th ed., United Kingdom: Oxford University Press.
6. Micklos, D. A., & Hilgert, U. (2013). Genome science: A practical and conceptual introduction, New York: Cold Spring Harbor Press.
7. Singh, V., & Dhar, P. K. (2020). Genome Engineering Via CRISPR-Cas9 System, United Kingdom: Academic Press.

8. Rastogi, S., & Pathak, N. (2013). Genetic engineering, United Kingdom: Oxford University Press.
9. Primrose, S. B., & Twyman, R. M. (2009). Principles of Gene Manipulation, United States: Blackwell Publishing.
10. Watson, J. D., Baker, T. A., & Bell, A. P. (2013). Molecular Biology of the Gene, 7th ed., United Kingdom: Pearson.

Course objectives:

This course enables the students to:

- Comprehend the fundamentals of enzyme nomenclatures, properties, and the methods for the discovery of novel enzymes.
- Gain in-depth knowledge about enzymes, which catalyse the diverse biochemical reactions in life processes, providing basic concepts of their, kinetics mechanism of action, regulation, inhibition, and wide-ranging applications.
- Understand the importance of enzymes as cellular catalysts.
- Appraise the applications of enzymes in industry, research and human health.

Course Outcomes:

On completion of this course, a student should be able to:

- Describe the structure, functions and the mechanisms of action of enzymes.
- Demonstrate the kinetics of enzyme catalyzed reactions and regulatory processes.
- Explain the different immobilization techniques and industrial and clinical scope of enzymes.
- Apply the principles of enzyme inhibitions in clinical research.

UNIT I**(14 hrs)**

Enzyme nomenclature and classification; Extraction and Purification of Enzymes: Extraction of soluble and membrane bound enzymes, purification of enzyme (Criteria for purity, assay of enzymes); Units of activity (IU and Katal); Structure and general properties of enzymes (Active site and specificity of enzymes); Theories of enzyme catalysis (Proximity and orientation, Acid-base catalysis, Nucleophilic and electrophilic reaction of enzymes); Factors affecting enzyme activity (Temperature, pH, time & substrate concentration).

UNIT II**(14 hrs)****Enzyme kinetics**

Enzymes Kinetics - Derivation of Michaelis Menton equation for single substrate reaction, Brigg's – Haldane modification. Lineweaver-Burk, Eddie-Hofstee and Hanes plot, Cornish Bowden plot.

Bisubstrate Reactions – Ping pong, random sequential and ordered sequential reaction types with specific examples (Cleland notation).

Co-enzymes. Advantages of multifunctional and multienzyme complexes- PDH Complex.

UNIT III

(14 hrs)

Enzyme inhibitions and novel enzymes

Inhibition kinetics –Competitive, non-competitive, uncompetitive, mixed inhibition. Irreversible inhibition – suicide inhibition & its significance. Primary and secondary plots in enzyme kinetics. Allosteric inhibition: Aspartate transcarbamoylase - Concerted and sequential models.

Zymogen activation - Digestive enzymes and blood clotting cascade.

UNIT IV

(14 hrs)

Mechanism of Enzyme action: Lysozyme; Chymotrypsin; Alcohol dehydrogenase; Synthetic enzymes; ribozyme; abzyme.

Diagnostic and clinical applications of enzymes: Transaminases; LDH & CK (Isozymes); Enzyme therapeutics; Immobilization of enzymes and enzymes in biosensors; enzyme engineering (Protein engineering- Subtilisin).

REFERENCES:

1. Aehle, W. (2008). Enzymes in industry-production and applications, Weinheim: Wiley-VCH.
2. Bowden, A. C. (2012). Fundamentals of Enzyme Kinetics, 4th ed., United Kingdom: Portland Press.
3. Devasena, T. (2014). Enzymology, India: Oxford University Press.
4. Garrett, R. H., & Grisham, C. M. (2017). Biochemistry, 6th ed., United Kingdom: Brooks/Cole.
5. Glick, B. R., Pasternak, J., & Patten, C. L. (2007). Molecular Biotechnology, principles and applications of recombinant DNA, 4th ed., Washington DC: ASM Press.
6. Young, M. M. (2019). Comprehensive Biotechnology, 3rd ed., United Kingdom: Pergamon Press Ltd.
7. Palmer, T. (2007). Enzymes, 2nd ed., United Kingdom: Horwood Publishing limited.
8. Price, N. C. (2016), Fundamentals of Enzymology. The cell & molecular biology of catalytic proteins, 5th ed., United Kingdom: Oxford University Press.
9. Taylor, K. B. (2013). Enzyme Kinetics and Mechanisms, Amsterdam: Kluwer Academic Publishers.
10. Voet, D., Voet, J. G., & Pratt, C. W. (2016). Fundamentals of Biochemistry, Life at the molecular level. 5th ed., USA: John Wiley & Sons Inc.

Course Objectives:

This course enables the students to:

- Impart hands-on-training in various techniques in genetic engineering.
- Acquire different methodologies in genetic engineering.
- Enable students to design a cloning experiment.
- Comprehend the application of Polymerase Chain Reaction.

Course Outcomes:

On completion of this course, a student should be able to:

- Isolate and purify genomic DNA/RNA.
- Demonstrate restriction digestion and ligation experiment.
- Standardize a PCR protocol for amplification of a specific target gene.
- Gather a thorough knowledge in genetic engineering methods practiced in research.

List of Practicals:

1. Extraction of DNA from plant tissue and purity determination with restriction digestion.
2. Agarose gel electrophoresis of DNA, RNA.
3. Isolation of Plasmids-electrophoretic identification of linear, circular and supercoiled DNA.
4. Restriction digestion of lambda DNA using EcoRI.
5. Ligation of restricted DNA of lambda phage using ligase.
6. Calcium chloride mediated transformation of *E.coli* & selection of transformants.
7. Restriction mapping.
8. PCR and determination of the molecular weight of product.
9. Southern blotting technique.
10. Demonstration of Realtime PCR.

Course Objectives:

This course enables the students to:

- Comprehend the principles of enzyme catalysed reactions.
- Learn the preparation of reagents, standard solutions and isolation of enzymes.
- Appreciate various qualitative and quantitative methods of enzyme assay.
- Execute a laboratory experiment using the standard methods and techniques, with the appropriate analysis and interpretation of data and results.

Course Outcome:

At the end of the course, a student should be able to:

- Design the experiments related to isolation and purification of enzymes.
- Apply and extend their knowledge and understanding of enzyme catalysis in research.
- Develop accurate skills in enzyme assays.
- Construct the standard curve, critically analyse the data and interpret the results.

List of Practicals:

1. Isolation and partial purification of enzyme – Urease/Acid phosphatase/invertase.
2. Qualitative method for salivary amylase.
3. Quantitative enzyme assay and specific activity calculation for salivary amylase.
4. Study of enzyme kinetics-effect of time.
5. Effect of temperature on enzyme activity and determination of activation energy.
6. Estimation of proteolytic activity.
7. Quantitative estimation of acid phosphatase.
8. Quantitative estimation of alkaline phosphatase.
9. Quantitative estimation of transaminases.
10. Enzyme Immobilization and enzyme assay.

Course Objectives:

This course enables the students to:

- Comprehend the purpose of research in academics.
- Understand the methodologies used to do research.
- Understand scientific communication.
- Appreciate scientific ethics.

Student Learning Outcomes:

At the end of the course, a student should be able to:

- Explain the differences between research methodologies.
- Design a small research project with appropriate research method.
- Apply correct ways of referencing to and citing from scientific literature.
- Analyze, contrast, compare and criticize scientific literature and write a research report/ thesis.

Unit I**(14 Hours)****Foundations of research and research ethics:**

History of science and science methodologies: Empirical science; scientific method; manipulative experiments and controls; deductive and inductive reasoning; descriptive science; reductionist vs holistic biology. Preparation for research choosing a mentor, lab and research question; maintaining a lab notebook.

Concepts of research: Definition of research, the need for research. Types of research - purpose driven and method based. Classification of Purpose driven research: Basic and Applied research. Classification of method-based research: historical, descriptive correlation, ex-post facto, experimental, case survey and content analysis.

Rights and obligations of Research Participants. Scientific conduct – ethics with respect to science and research, intellectual honesty and research integrity. Scientific misconduct – falsification, fabrication and plagiarism. Software for detecting plagiarism. Publication ethics – meaning and importance, conflicts of interest, publication misconduct – types of publication misconduct, identification of publication misconduct, complaints and appeal.

Unit II

(14 Hours)

Research methodology

Selecting and defining a research problem: Criteria for selecting a problem, formulating and testing the hypothesis. Literature review: web browsing for information search; search engines; hidden web and its importance in scientific research.

Research design – Experimental and Nonexperimental research design, Field research, and Survey research. Methods of data collection – Secondary data collection methods, qualitative methods of data collection, and Survey methods of data collection. Attitude measurement and scaling – Types of measurement scales; Questionnaire designing – Reliability and Validity. Sampling techniques – The nature of sampling, Probability sampling design, Nonprobability sampling design, Determination of sample size. Processing and analysis of data, applying computer software for statistical calculations and interpreting results and drawing conclusions. Representation of data.

Unit III

(14 Hours)

Scientific communication

Scientific writing skills - importance of communicating science;

Types of reports- research reports/ thesis. Elements of a scientific paper including abstract, introduction, materials & methods, results-presentation of data: tables/figures, tests of statistical significance, discussion, references; styles for citing references, Mendeley software, drafting titles; Guidelines on Authorship, Copy right form.

Publishing scientific papers – journal finder, Data bases – indexing data base, citation data base, Web of science, Scopus etc, Research Metrics – Impact Factor of Journal as per Journal Citation Report, SNIP, SJR, IPP, Cite Score; Metrics – h-index, g-index, i10 index, Altmetric. Formatting the paper as per instructions of the journal, submission, peer review process, open access. Predatory publishers and journals – software to identify predatory publications.

Scientific presentations- scientific poster preparation & presentation; PowerPoint presentation and defending interrogation. Writing research grant proposals.

REFERENCES:

1. Hochberg, M. (2019). An Editor's Guide to Writing and Publishing Science, United Kingdom: Oxford University Press.
2. Johnson, S., & Scott, J. (2019). Study and Communication Skills for the Biosciences,

- 3rd ed., United Kingdom: Oxford University Press.
3. Sapsford, R., & Jupp, V. (2008). Data Collection and Analysis, 2nd ed., India: SAGE Publications Inc.
 4. Kothari, S. R. (2012). Research Methodology Methods and Techniques, New Age: New Age International (P) Ltd.
 5. Matthews, J. R., & Matthews, R. W. (2021). Successful Scientific Writing (A Step-by-Step Guide for the Biological and Medical Sciences), 4th ed., United Kingdom: Cambridge University Press.
 6. Muralidhar, K., Ghosh, A., & Singhvi, A. K. (2019). Ethics in Science Education, Research and Governance, India: Indian National Science Academy (INSA).
 7. Prathapan, K. (2019). Research Methodology for Scientific Research, India: Wiley.
 8. Ruxton, J. D., & Colegrave, N. (2016). Experimental Design for the Life Sciences, 4th ed., United Kingdom: Oxford University Press.
 9. Sharma, M. (2011). Research Methodology and Scientific Communication, VDM Verlag.
 10. Wayne, C. B., Colomb, G. C., & Williams, J. M. (2008). The Craft of Research, 3rd ed., Chicago: The University of Chicago Press.

Course Objectives:

This course enables the students to:

- Design a blueprint for the analysis of biomolecules using various analytical techniques.
- Demonstrate the principles and instrumentation of various chromatographic, spectroscopic methods used in biotechnology.
- Interpret the results of various bio analytical techniques scientifically.
- Describe the role of microscopy and radioisotopes in the visualization of cellular components and macromolecules.

Course Outcomes:

At the end of the course, a student should be able to:

- Discuss the principle and instrumentation of HPTLC, HPLC, GC for identification, and characterization of compounds.
- Apply the principles and theory of UV-Vis spectroscopy, MS (MALDI-TOF and LC-MS/MS), NMR and XRD for the identification and characterization of organic compounds.
- Select an appropriate method of centrifugation or electrophoresis for the separation and identification of analyte molecule by applying the theory and principle of various methods of centrifugation and electrophoresis.
- Explain the application of radioisotopes in biology and Instrumentation of Geiger-Muller counter and Solid, Liquid scintillation counters and autoradiography for detection of radio activity.

Unit I

(16 hrs)

Chromatography & Spectroscopy

Chromatography: Paper chromatography, TLC and HPTLC; Chromatographic methods for macromolecule separation-Gel permeation, Ion exchange, Affinity chromatography, Gas chromatography. HPLC. Spectroscopy: Laws of light absorption- Beer - Lambert's law. Theory, instrumentation and application of: UV-Vis spectroscopy, Mass spectrometry (MALDI-TOF and LC-MS/MS), Nuclear Magnetic Resonance (NMR), X-ray diffraction.

Unit II

(16 hrs)

Centrifugation & Electrophoresis

Centrifugation- Basic principles, Mathematics & theory (RCF, Sedimentation coefficient etc); Types and applications - Microcentrifuge, High speed & Ultracentrifuges; Preparative centrifugation- Differential, density gradient, rate zonal, isopycnic centrifugation; factors affecting centrifugation. Electrophoresis – Theory and factors affecting. Zone electrophoresis; paper and cellulose acetate.

Gel electrophoresis: Polyacrylamide and Agarose gel electrophoresis; isoelectric focusing, 2D- Electrophoresis; Gradient electrophoresis; Pulsed field gel electrophoresis.

Unit III

(16 hrs)

Radioisotopes and Microscopy in Biology

Radioactivity: 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); Autoradiography. Applications of isotopes: radiotracer techniques, distribution studies, isotope dilution technique, metabolic studies, clinical application.

Resolving powers of different microscopes, Fluorescent microscopy, Confocal microscopy, Transmission and scanning electron microscopic techniques (TEM, SEM & AFM) - Preparation of samples and their applications; freeze-etch and freeze-fracture methods for EM.

REFERENCES:

1. Jackson, M. B. (2006). Molecular & Cellular Biophysics, United Kingdom: Cambridge University Press.
2. Khopkar, S. M. (2008). Basic Concepts of Analytical Chemistry, 3rd ed., India: New Age Publications.
3. Pattabhi, V., & Gautham, N. (2003). Biophysics, United States of America: Kluwer Academic Publisher.
4. Robards K., Jackson P. E., & Haddad, P. A., (2004). Principles and Practice of Modern Chromatographic Methods, United States of America: Elsevier Ltd.
5. Scopes, R. (1994). Protein Purification - Principles & Practices, 3rd ed., New York: Springer Science + Business Media.

6. Trivedi, P. (2010). Electron Microscopy, 1st ed., United Kingdom: Oxford Book Company.
7. Upadhyay, A., Upadhyay, K., & Nath, N. (2005). Biophysical Chemistry-Principles and Techniques, India: Himalaya Publishing House.
8. Viswanathan, P., (2011). Electron Microscopy, 1st ed., Tamil Nadu: MJP Publishers.
9. Wilson, K., & Walker, J. (2000). Principles and Techniques of Practical Biochemistry, 5th ed., United Kingdom: Cambridge University Press.

Course Objectives:

This course enables the students to:

- Provide information on the use of common computational tools and databases which facilitate investigation of molecular biology, evolution-related concepts and protein structure prediction.
- Teach genomics, proteomics and metabolomics and their applications in modern biology.
- Impart knowledge on various protein and metabolomics databases and their role in data analysis.
- To learn about the use of freely available WGS analysis tools and how to use some of these tools to analyse the WGS data.

Course Outcomes:

Students should be able to:

- Gain knowledge of various computational tools and methods in bioinformatics.
- Discern the crucial concepts and techniques applied in genomics, transcriptomics and proteomics.
- Understand the importance of genomics, proteomics, metabolomics and their applications in various applied areas of biology.
- Formulate and assess experimental design for solving theoretical and experimental problems in Genomics, Proteomics and metabolomics.

UNIT I**(14 hrs)****Bioinformatics – An Introduction**

Online tools for bioinformatics, Biological databases: The nucleotide and protein sequence databases, primary and secondary databases. Sequence Analysis- Orthology prediction (comparative genomics), FASTA, BLAST. Molecular phylogenetics: Molecular Evolutionary Genetics Analysis (MEGA), Search for transcription factor binding sites (TFBS), Computational prediction of miRNA target genes.

UNIT II

(14 hrs)

Proteogenomics: Concepts and principles of genome annotation, genome search specific peptides, alternative translation initiation, small ORFs, Analysis of transcriptomic and proteomic data for genome annotation; Gene prediction algorithms. Proteomic analysis tools, Protein databases metabolomic databases and tools, metabolic dataset and tools, metabolic pathways resources: KEGG, Reactome.

Quantitative and Targeted Proteomics: Introduction to quantitative proteomics- Differential proteomics, post-translational modifications, Targeted proteomics- Parallel reaction monitoring, Multiple reaction monitoring, Targeted proteomics software- Skyline.

UNIT III

(14 hrs)

Concepts of Proteomics and Metabolomics

Metabolites and Metabolomics Metabolomics-an overview, basic sample preparation strategies- extraction, derivatization, Workflow for lipidomics; Introduction to mass spectrometry and modes of data acquisition, data repositories. Metabolomic Data Analysis: Peak detection, retention time alignment; identification of molecular features and metabolites; structural confirmation of metabolites. Software- Multiquant, MZmine, XCMS, MarkerView, LipidSearch. Metabolic pathways and inborn errors of metabolism.

REFERENCES:

1. Bagchi, D., Swaroop, A., & Bagchi, M. (2015). Genomics, Proteomics and Metabolomics in Nutraceuticals and Functional Foods, 2nd ed., United Kingdom: Wiley-Blackwell.
2. Baxevanis, A. D., & Ouellette, B. F. F. (2005). Bioinformatics – A practical guide to the analysis of genes and proteins, 3rd ed., India: John Wiley & Sons.
3. Harisha, S. (2010). Fundamentals of Bioinformatics, 1st ed., Bangalore: I. K. International Pvt. Ltd.
4. Josip, L. J. (2011). Introducing Proteomics: From Concepts to Sample Separation, Mass Spectrometry and Data Analysis, 1st ed., United Kingdom: Wiley-Blackwell.
5. Knapp, J. S., & Cabrera, W. L. (2011). Metabolomics: Metabolites, Metabonomics, and Analytical Technologies, 1st ed., New York: Nova Science Publishers.
6. Krane, D. E., & Raymer, M. L. (2002). Fundamental Concepts of Bioinformatics, 1st ed., San Francisco: Benjamin Cummings.
7. Merz Jr, K. M., Ringe, D., & Reynolds, C. H. (2010). Drug Design: Structure- and Ligand- Based Approaches, 1st ed., United Kingdom: Cambridge University Press.

8. Mount, D. W. (2004). Bioinformatics: Bioinformatics Sequence and Genome Analysis, 2nd ed., New York: Cold Spring Harbor Laboratory Press.
9. Simpson, R. (2002). Proteins and proteomics: A laboratory manual, New York: Cold Spring Harbor Laboratory Press.
10. Twyman, R. M. (2014). Principles of Proteomics, 2nd ed., New York: Garland Science.

Course Objectives:

This course enables the students to:

- Comprehend the concepts in biosafety and appreciate them.
- Recognize the importance of safe handling of pathogenic organisms in laboratories and during transport.
- Foster a better understanding of biosafety guidelines and regulations.
- Examine the ethical issues in biological research.

Course Outcome:

At the end of the course, a student should be able to:

- Evaluate biosafety and bioethics in the context of modern biotechnology.
- Describe the standard operating procedures for biotechnology research and assign Biosafety levels.
- Appraise the relevance of different international agreements and protocols for biosafety.
- Develop the skills to think critically about risks and risk mitigation strategies needed in their own scientific environment.

UNIT I**(16 hrs)****Biosafety**

Principles of biosafety; Procedures and Good Laboratory Biosafety Practices; Benefits and concerns/risks of Biotechnology; Concepts of Biohazards, Bioterrorism, GMOs and LMOs; Designing of containment facilities (Laboratories, biosafety cabinets, greenhouses); Assigning of biosafety levels; Biosafety levels of specific microorganisms, infectious animals; Standard Operating Procedures (SOPs) for research involving microbes and recombinant DNA; Principles of safety assessment of transgenic plants: Sequential steps in risk assessment.

UNIT II**(16 hrs)****Biosafety guidelines and regulations**

International regulations (Cartagena protocol; OECD consensus documents; Biological Weapons Convention); Role of Indian regulations (EPA act and rules; Regulatory

framework: RCGM, GEAC, IBSC and other regulatory bodies); Guidelines of State Government for field trials (GMOs) or Environmental release of GMOs; GM labeling: Food Safety and Standards Authority of India (FSSAI); Responsible waste disposal (Medical waste, research lab, industrial waste).

UNIT III

(16 hrs)

Bioethics

Bioethics in Biotechnology and Healthcare: Introduction to bioethics; Ethical issues involved in: Molecular technologies, genetic manipulations, germline therapy and transgenics; Human genome project and its ethical issues; Human cloning and bioethics; GM food: Controversies and global food ethics; Social and ethical implications of biological weapons. Benefit Sharing and Informed Consent; Independent Ethics Committee; Constitution of institutional ethics committee; Conflicts of Interest.

Ethical dimensions of IPR: Application of IPR regime to Biological Resources and Biopiracy, Access to Biological Resources.

REFERENCES:

1. Bryant J., Velle, L. B., & Searle, J., (2002). Bioethics for Scientists, England: John Wiley & Sons Ltd.
2. Goel, D., & Parashar, S., (2013). IPR, Biosafety and Bioethics. Delhi: Pearson.
3. Joshi, R. (2006). Biosafety and Bioethics. Delhi: Isha Books.
4. Krishna, V. S. (2007). Bioethics and Biosafety in Biotechnology. New Delhi: New Age International Publishers.
5. Kuhse, H., Schüklenk, U., & Singer, P. (2016). Bioethics: An Anthology, 3rd ed., United Kingdom: John Wiley & Sons, Inc.
6. Nambisan, P. (2017). An Introduction to Ethical, Safety and Intellectual Property Rights Issues in Biotechnology. India: Academic Press (Elsevier).
7. Post, S. G. (2004). Encyclopedia of Bioethics (Five Volumes), 3rd ed., USA: Macmillan Reference.
8. Talbot, M. (2012). Bioethics: An Introduction. Delhi: Cambridge University Press.
9. Vaughn, L. (2019). Bioethics: Principles, Issues and Cases, 4th ed., New York: Oxford University Press.

10. Weidmann, M., Silman, N., Butaye, P., Elschner, M. (2014). Working in Biosafety Level 3 and Level 4 Laboratories, A Practical Introduction. Germany: Wiley Blackwell.

PS 509.2 P RESEARCH METHODOLOGY AND SCIENTIFIC COMMUNICATION PRACTICALS

Course Objectives:

This course enables the students to:

- Identify the importance of research in Biosciences.
- Conduct/manage research with integrity.
- Assess plagiarism using the software.
- Communicate the scientific findings.

Course Outcomes:

At the end of the course, a student should be able to:

- Explain key research designs and techniques.
- Identify various sources of information for literature review.
- Read, comprehend, and explain research articles in their academic discipline.
- Collect, analyze and represent their data and write a research report/ thesis.

List of Practicals:

1. Write a research proposal.
2. Construct questionnaire.
3. Statistical analysis of data using software.
4. Representation of Data.
5. Critical analysis of a research paper.
6. Make a poster presentation.
7. Make an oral presentation based on a research paper.
8. Write a review article on a topic relevant to their program of study.
9. Use Turnitin software to check for plagiarism.
10. Submit the review article to a suitable journal.

PS 510.2 P ANALYTICAL TECHNIQUES IN BIOTECHNOLOGY PRACTICALS

Course Objectives:

This course enables the students to:

- Demonstrate the handling and applications of various spectrophotometric techniques in biological investigations.
- Describe the principles and procedure of Electrophoresis and SEM in biological investigations/experiments.
- Understand and apply the principle and procedure of TLC and gel filtration chromatography for detection and purification of analyte molecules.
- Select appropriate analytical technique to design the experiment.

Course Outcome:

At the end of the course, a student should be able to:

- Perform the identification and characterization of various biomolecules using UV Vis spectroscopy, AAS and flame photometry.
- Demonstrate the strengths, limitations and use of various chromatographic techniques including paper, TLC, gel filtration and HPLC for the analysis of various biomolecules.
- Interpret and analyse the result obtained from various colorimetric assays of protein by plotting a standard curve.
- Examine the topography, morphology and composition of various samples by creating the 3D images using SEM.

List of Practicals:

1. Ascending paper chromatography for separation of amino acids
2. Two-Dimensional Paper Chromatography
3. TLC for the separation and identification of carbohydrates.
4. To determine an unknown protein concentration by plotting a standard graph of BSA using UV-Vis Spectrophotometer and validating the Beer- Lambert's Law
5. Estimation of Protein by Bradford method
6. Gel filtration chromatography
7. SDS-PAGE and estimation of molecular weight of Proteins
8. Flame Photometry
9. Elemental Analysis using AAS.
10. SEM
11. HPLC

Course Objectives:

This course enables the students to:

- Learn about the bioinformatics databases, databanks, data format and data retrieval from the online sources.
- Comprehend the features of the databases of local and multiple alignments.
- Understand how to construct phylogenetic tree and its interpretation.
- Understand the methods of whole genome sequencing.

Course Outcomes:

At the end of the course, a student should be able to:

- Assess the nucleotide sequence data of the given species using NCBI/ EMBL/ DDBJ.
- Analyse the protein sequence of the species using PIR and Swissprot/ UniProt.
- Predict the structure of protein using PDB. View the 3D structure of a protein using RASMOL software.
- Carry out the multiple sequence alignment of the proteins with Clustal OMEGA. Search the database of proteins/ nucleic acids using BLAST program.

List of Practicals:

1. Gene Structure and Function prediction.
2. ORF Prediction.
3. Sequence Similarity Searching.
4. Multiple sequence Alignment.
5. Primer designing.
6. Molecular Phylogeny.
7. Analysis of Nucleic Acid Sequences.
8. Search protein sequence using PIR and Swissprot / UniProt.
9. Protein structure prediction using PDB and view the 3D structure of a protein using RASMOL software.
10. Whole genome sequencing, assembly and annotation.

Course Objectives:

This course enables the students to:

- Evaluate the importance, care, maintenance, life-span and responsible disposal of Personal Protective Equipment.
- Comprehend the design in containment laboratories.
- Critically analyze the ethical issues associated with scientific research and practice in biotechnology.
- Endorse bioethics while creating an intellectual property right.

Course Outcomes:

At the end of the course, a student should be able to:

- Demonstrate good laboratory procedures and practices.
- Examine the design of confinement facilities at different Biosafety levels.
- Apply the risk analysis framework to their own or their peers' scientific activities.
- Develop a research career in the relevant area, to handle various situations he/she encounters, with adequate caution and care.

List of Practicals:

1. Safety in research laboratory by donning Personal Protective Equipment.
2. Disinfection and Decontamination of the laboratory.
3. Mock transport of infectious substances.
4. Assessment of laboratory safety using the WHO formulated safety checklist.
5. Field Trip to Viral Research Centre to evaluate the biosafety laboratory set-up.
6. Analyzing and Managing risks in life science research through case studies.
7. Responsible waste management practices.
8. Planning of establishing a hypothetical biotechnology industry in India.
9. A case study on clinical trials of drugs in India with emphasis on ethical issues.
10. Mock trial case on Infringement of IPR.

**PO 513.2 QUALITY ASSURANCE AND QUALITY CONTROL IN
PRODUCT DEVELOPMENT HOURS: 48**

This course enables the students to:

- Course Outcomes:**

At the end of the course, a student should be able to:

- Apply quality tools for quality management and main guidelines & requirements of GMP thus contributing to the organization when it comes to understanding industry standards.
- Integrate the principles of the GMP quality system and quality control and the important procedures when dealing with complaints and recalls.
- Justify the requirements for good documentation practice and complete appropriate documents in compliance with regulatory guidelines.
- Execute and adopt quickly into the GMP environment.

UNIT 1: (16 hrs)

Quality assurance and control

Basic principles of QA and QC. Guidelines for QA and QC, The role of the quality manager.

Quality systems: ISO 9000 series; ISO 14000 series; ISO 22000, HACCP. Use of the quality systems approach within the pharmaceutical industry: Quality systems inspection technique (QSIT), Total Quality Management and Process steps of Total Quality Management (TQM), Deviation & change management, Corrective And Preventive Actions (CAPA), Quality Risk Management (QRM) and Quality by design (QbD).

Quality tools and techniques: Tools for identification of problems; Tools for the analysis of problems; Benchmarking; Using the tools and techniques (Type of quality teams, Team working – the problem-solving approach, Team working – the process skills).

UNIT II: (16 hrs)

Introduction to GMP

Historical background, principles of GMP, introduction to cGMP, Schedule M and Schedule T

Personnel (Key personnel, Background and duties of the qualified person, Personnel training and hygiene), Premises and equipment, Concepts of equipment qualification and validation-Validation Master Plan (VMP). General principles-Prevention of cross-contamination in production. Self- inspection.

UNIT III: (16 hrs)

Good documentation practices and Release of Finished product:

Fundamentals of Good Documentation Practices, data integrity requirements. Document types (Commitment documents, Directive documents and Record documents). Recording and retention of documents; Manufacturing Documents, Master Formula, Batch Formula Records, Quality audits, Site master file. Standard operating procedures for various operations. How to correct errors and omissions in data entry.

Quality review, Quality audits, Batch release document. Complaints and Recalls: Evaluation of complaints, Recall procedures. Counterfeit pharmaceutical product.

REFERENCES:

1. Cooper, B. N. (2017). Good Manufacturing Practices for Pharmaceuticals-GMP in Practice. California: Create Space Independent Publishing Platform.
2. James, P. A., & Frederick, J. C. (2007). Validation of Pharmaceutical Processes, New York: CRC Press.
3. Jordi, B. (2015). Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook, United Arab Emirates: Bentham Science Publishers.
4. McCormick, K. (2002). Quality, Pharmaceutical Engineering Series, Oxford: Butterworth- Heinemann.

5. McDowall, R. D. (2018). Data Integrity and Data Governance Practical Implementation in Regulated Laboratories, United Kingdom: Royal Society of Chemistry.
6. Nancy, R. T. (2005). The Quality Toolbox, United States of America: ASQ Quality Press.
7. Rick, N. G. (2004). Drugs from discovery to approval. New Jersey: John Wiley & Sons.
8. Subrahmanyam, C. V. S. (2015). Pharmaceutical Production and Management, 2nd ed., New Delhi: Vallabh Prakashan.
9. Sharma, P. P. (2004). How to Practice GMPs, 4th ed., Delhi: Vandana Publications Pvt. Ltd.
10. Syed, I. H. (2002). Pharmaceutical Master Validation Plan: The Ultimate Guide to FDA, GMP, and GLP Compliance, United States: St. Lucie Press.

Course Objectives:

This course enables the students to:

- Categorize insight on the various aspects biotechnological processes and its applicative value in pharmaceutical and agriculture industries.
- Comprehend the production of transgenic animals, gene therapy and to become familiarize with the ethical practices in animal biotechnology.
- Appreciate the trends in plant and microbial biotechnology and its applications in human welfare.
- Examine the application of biochemical and molecular markers in molecular diagnostics.

Course Outcomes:

On completion of the course, a student should be able to:

- Demonstrate deep understanding of various methods for gene transfer, gene therapy and *in vitro* fertilisation of animals.
- Discuss and analyze scientific questions related to transgenic plants, role of microbes in industry and agriculture.
- Implement the techniques used in molecular diagnostics.
- Evaluate the biosensor technology in Healthcare, Food technology and Environmental monitoring.

Unit I**(16 hrs)**

Animal Biotechnology: *In-vitro* fertilization and embryo transfer in humans and livestock-principle, methods and applications.

Animal genetic engineering: Various methods of gene transfer; application of transgenic animals for pharmaceutical and therapeutic purposes; Gene therapy-somatic and germline gene therapy. Mechanism of gene therapy-gene augmentation, gene correction and gene silencing; Ethical issues related to animal biotechnology.

Unit II**(16 hrs)**

Microbial Biotechnology: A brief account of microbes in industry and agriculture, Metabolic engineering for over production of metabolites.

Plant Biotechnology: Introduction to plant tissue culture and its applications, Gene transfer methods in plants, Transgenic plants -A brief introduction, Potential GMO Applications and public concerns.

Unit III

(16 hrs)

Introduction and Concept of Molecular Diagnostics: DNA diagnostics: conventional and real time PCR in diagnostics. Biochemical and molecular markers of disease diagnosis and their applications.

Biosensors: Concept, principle and applications in Health and medicine, Food technology and Environmental monitoring.

REFERENCES:

1. Brown, T. A. (2012). Gene Cloning and DNA Analysis: An Introduction, 6th ed., United Kingdom: Blackwell Science.
2. Chawla, H. S. (2020). Introduction to Plant Biotechnology, 2nd ed., India: Oxford and IBH Publishing.
3. Demain, A. & Davis, J. E. (2011). Manual of Industrial Microbiology & Biotechnology, 3rd ed., Washington DC: ASM Press.
4. Dutta, R. C., & Dutta, A. K. (2018). 3D Cell Culture: Fundamentals and Applications in Tissue Engineering and Regenerative Medicine, United Arabs Emirates: Jenny Stanford Publishing.
5. Glick, B. R., & Pasternak, J. J., (2010). Molecular Biotechnology: Principles and Applications of Recombinant DNA. Washington, D.C.: ASM Press.
6. Glick, B. R., & Patten C. L. (2017). Molecular Biotechnology: Principles and Applications of Recombinant DNA 5th ed., Washington, D.C.: ASM Press.
7. Panno, J. (2010). Animal Cloning: The Science of Nuclear Transfer, Revised ed., New York: Facts on File Inc.
8. Primrose, S. B., & Blackwell, T. R. (2010). Principles of Gene Manipulation, 8th ed., United States: Wiley-Blackwell.
9. Stanburry, P. F., & Whitaker, A. (2005). Principles of Fermentation Technology, 2nd ed., Pergamon Press, Butterworth Heinemann-Elsevier.
10. Stocum, D. L. (2012). Regenerative Biology and Medicine, 2nd ed., United States: Academic Press.

SEMESTER – III

PH 501.3

ANIMAL BIOTECHNOLOGY

Hours:56

Course Objectives:

This course enables the students to:

- Describe laboratory design.
- Gain hands on knowledge of the various animal cell culture techniques.
- Understand the applications of animal biotechnology.
- Meet the challenges of the new and emerging areas of biotechnology industry.

Course Outcomes:

At the end of the course, a student should be able to:

- Demonstrate aseptic techniques and good laboratory practices.
- Describe the bioprocess technology for economically important products.
- Apply the knowledge for improvement of farm animals.
- Take up animal based biological research /relevant biotech industry.

UNIT I

(14 hours)

Animal tissue culture techniques

Laboratory design, aseptic techniques, Equipment and materials for animal cell culture. Physical environment for cell growth –temperature, pH, osmolarity, CO₂, substratum. Different constituents of culture medium, types of media and their application. Basic techniques of mammalian cell culture *in vitro*; disaggregation of tissue, cell separation techniques. Measurement of viability and cytotoxicity. Initiation of primary culture. Detection of contaminants- mycoplasma, bacterial and fungal. Eradication of contaminations. Cell lines-characteristics and routine maintenance. Characterization of the cultured cells, measuring parameters of growth. Cell cloning, cryopreservation and cell banking.

UNIT II

(14 hours)

Animal Cell Culture applications

Cell synchronization, Somatic cell fusion, detection of hybrids and applications. Three-dimensional culture -Organ and histotypic cultures;
Stem cells: Characteristics of various types - Adult (mesenchymal, peripheral and chord blood) and embryonic stem cells. Induced pluripotent stem cells. Stem cell-based therapies,

Tissue engineering: scaffolds- natural and synthetic, sources of cells, methodology with example of skin and cartilage. 3D Bioprinting.

UNIT III

(14 hours)

Products from animal cell culture

Cell Lines for used for Biotechnological applications.

Biopharmaceuticals produced in Mammalian cell culture systems: Hormones and growth factors- human growth hormone, erythropoietin, Therapeutic enzymes- Tissue plasminogen activator, Urokinase, Blood coagulation factors- Factor XIII. Animal cell cultures for baculovirus production.

Cell culture-based viral vaccines: current status and future prospects

Culture of fish and crustacean cells and their applications: Culture of Pearl oyster mantle cells to produce pearls. Lab grown meat.

UNIT IV

(14 hours)

Applications of Biotechnology in improvement of animals

Assisted reproductive technologies (ART), *In vitro* fertilization (IVF) - Fertilization by means of micro insemination, PZD, ICSI, SUZI, MESA and embryo transfer (ET) in humans. Manipulation of reproduction in animals.

Animal cloning - reproductive cloning, therapeutic cloning, xenotransplantation.

Transgenic Animals: Methodology, Embryonic Stem Cell method, Microinjection method, Retroviral vector method, Applications of transgenic animals with examples- cattle, poultry, fish and silk worms. Animals as bioreactors-biopharming.

Gene therapy-somatic and germline gene therapy. Mechanism of gene therapy-gene augmentation, gene correction and gene silencing.

REFERENCES:

1. Carter, M., & Hunt, J. (2018). Animal Cell Culture, 1st ed., United Kingdom: Ed-Tech Press.
2. Castilho, L. R., Moraes, A. M., Elisabeth, F. P., Augusto, E., & Butler, M. (2007). Animal Cell Technology: From Biopharmaceuticals to Gene Therapy 1st ed., New York: Garland Science, Taylor & Francis group.
3. Clark, D. P., & Pazdernik, N. J. (2009). Biotechnology Applying the genetic revolution,

USA: Elsevier Academic Press.

4. Dutta, R. C., & Dutta, A. K. (2018). 3D Cell Culture: Fundamentals and Applications in Tissue Engineering and Regenerative Medicine, Singapore: Jenny Stanford Publishing.
5. Fisher, J. P., Mikos, A. G., Bronzino, J. D., & Peterson, D. R. (2017). Tissue Engineering: Principles and Practices, 1st ed., Boca Raton: CRC Press.
6. Freshney, R. I. (2016). Culture of Animal Cells: A Manual of Basic Technique and Specialized Applications, 7th ed., United States: Wiley-Blackwell
7. Glick, B. R., & Patten, C. L. (2017). Molecular Biotechnology: Principles and Applications of Recombinant DNA 5th ed., United States of America: ASM Press.
8. Meyer, U., Meyer, T., Handschel, J., & Weismann, H. P. (2009). Fundamentals of Tissue Engineering and Regenerative Medicine, Germany: Springer-Verlag Berlin Heidelberg.
9. Panno, J., (2010). Animal Cloning: The Science of Nuclear Transfer, Revised ed., New York: Facts on File Inc.
10. Primrose, S. B., & Blackwell, T. R. (2010). Principles of Gene Manipulation by Pub.; 8th ed., United States: Wiley-Blackwell.

Course Objectives:

This course enables the students to:

- Acquire information about design of plant tissue culture lab, culture environment, learn varied sterilization techniques.
- Comprehend the principles, methods and application of plant tissue culture.
- Acquire knowledge about molecular markers in plant breeding and computational tools and resources in plant genome informatics.
- Describe the application of genetically modified plants in crop improvement, get exposure about gene editing and methods involved.

Course Outcomes:

At the end of the course, a student should be able to:

- Understand the organization of plant genome and intergenomic interaction.
- Appraise various methods of marker assistant selection in plant breeding.
- Describe various genes used in plant transformation and the role of transgenic plants in human welfare.
- Translate the concepts in future studies and debate on the issue related to GMOs and evaluate its significances

UNIT I**(14 hrs)****Plant tissue culture-1**

Laboratory design, Media for tissue culture- various components of culture media and types - Preparation of MS media, Plant Growth Regulators- Role of Auxin, Cytokinin, Gibberellins, Brassinosteroids (BRs). Sources of contaminants and various sterilization techniques, Totipotency, Callus culture. Organogenesis, Somatic embryogenesis and Artificial Seeds.

UNIT II**(14hrs)****Plant tissue culture-II**

Micro propagation: Various stages in micropropagation, production of virus-free plants, Protoplast isolation and culture, somatic hybrids and cybrids. Haploid production: anther/ pollen and ovary/ ovule culture. Embryo culture, Somaclonal variations-production and

applications. Cell suspension cultures, hairy root culture, Production of secondary metabolites and biotransformation.

UNIT III

(14hrs)

Molecular markers and mapping techniques in plant improvement:

Molecular markers: RAPD, AFLP, RFLP, SSR, SNP, ISSR and SCAR. QTL mapping. High throughput genotyping, synteny mapping, plant DNA barcoding, Computational tools and resources in plant genome informatics. Advanced methodologies - cisgenesis, intragenesis.

UNIT IV

(14hrs)

Genetically Modified Plants

Development of transgenic plants for virus resistance, bacterial and fungal disease resistance, GM plants for insect resistance (e.g. BT cotton, BT brinjal), Golden rice, Flvr-savr tomato. Seed terminator technology, Engineering of chloroplast genome, Gene editing with TALEN and CRISPER-Cas technology.

REFERENCES:

1. Bajaj, Y. P. S. (2007). *Biotechnology in Agriculture and Forestry*, Berlin: Springer-Verlag.
2. Bhojwani, S. S., & Razdan, A. (1996). *Plant Tissue Culture: Theory and Practice*, Netherlands: Elsevier Science.
3. Brown, T. A. (2010). *Gene Cloning and DNA Analysis: an Introduction*, 6th ed., Oxford: Blackwell Pub.
4. Buchanan, B. B., Gruissem, W., & Jones, R. L. (2015). *Biochemistry and Molecular Biology of Plants*, 2nd ed, United States: Wiley Blackwell.
5. Chawla, H. S. (2020). *Introduction to Plant Biotechnology*, 3rd ed., India: Oxford and IBH Publishing Company Pvt. Ltd.
6. Glick, B. R., & Pasternak, J. J. (2010). *Molecular Biotechnology: Principles and Applications of Recombinant DNA*. Washington, D.C.: ASM Press.
7. Razdan, M. K. (2003). *Introduction to Plant Tissue Culture*. India: Oxford and IBH Publishing Company Pvt. Ltd.
8. Satyanarayana, B. N., & Varghese, D. B. (2007). *Plant tissue culture practices and new experimental protocols*, India: Wiley.

9. Slater, A., Scott, N. W., & Fowler, M. R. (2008). *Plant Biotechnology: An Introduction to Genetic Engineering*. Oxford: Oxford University Press.
10. Walters, D. R. (2011). *Plant Defense: Warding off attack by pathogens, herbivores and parasitic plants*, United Kingdom: Wiley-Blackwell Publishing Ltd.

Course Objectives:

This course enables the students to:

- Impart hands-on-training in sterilization of laboratory.
- Acquire expertise in various sterilization techniques.
- Make the reagents, media.
- Prepare various types of tissues/cells for culture.

Course Outcomes:

At the end of the course, a student should be able to:

- Apply Good Laboratory practices and aseptic techniques.
- Initiate primary explant culture and maintain cell lines.
- Isolate cells from tissues.
- Determine cytotoxicity and growth kinetics.

List of Practicals:

1. Fumigation of the laboratory.
2. Preparation of media and balanced salts solutions.
3. Primary explant culture & Observation under inverted microscope.
4. Estimation of Total cell count & cell viability by Dye exclusion method.
5. Isolation of peripheral blood lymphocytes by density gradient centrifugation.
6. Staining for suspension culture.
7. Staining for monolayer culture.
8. Initiating CHO cell line culture- monolayer culture.
9. Growth kinetics (calculation).
10. Estimation of cytotoxicity of a drug (calculations).

Course Objectives:

This course enables the students to:

- Acquire knowledge about layout of plant tissue culture lab, culture environment, learn varied sterilization techniques.
- Impart hands-on-training in anther culture and micropropagation of plants.
- Comprehend protoplast isolation, purification and culture techniques.
- Understand RAPD marker assisted selection of plants for crop improvement.

Course Outcomes:

On completion of this course, a student should be able to:

- Apply Good Laboratory practices and aseptic techniques.
- Prepare the media and other reagents, initiate primary cell culture, Estimate the viability of cells as well as cell concentration.
- Perform identification of correct stage of anther for haploid culture and establish and the establishment of secondary embryogenic tissues.
- Apply knowledge for large scale clonal propagation of plants through various micropropagation techniques.

List of Practicals:

1. Laboratory organization.
2. Establishing callus cultures and studies of morphogenetic and non-morphogenetic calli.
3. Subculturing of callus for cell suspension cultures.
4. Micropropagation using axillary meristems.
5. Protoplast culture.
6. Haploid culture.
7. Synthetic seeds.
8. DNA isolation and RAPD analysis.
9. Antimicrobial properties of secondary metabolites from plant extracts.
10. Cryopreservation and germination of embryos.

Course objectives:

This course enables the students to:

- Infer the need for sustainable innovation, and how biotechnology and biobased production can contribute to this.
- Comprehend the isolation and strain improvement of microorganisms of potential industrial interests.
- Impart knowledge on design and operation of fermentation processes with all its prerequisites.
- Understand various downstream processing for product recovery.

Course Outcomes:

At the end of the course, a student should be able to:

- Explain the screening, strain improvement and design of fermentation media.
- Assess the conditions for efficient and sustainable design of bioprocesses.
- Integrate scientific and technological knowledge on the use of bioprocesses for industrial products on the cell and process level.
- Analyze the processes and their application in healthcare, agriculture, energy and the environment.

UNIT I**(16 hrs)****Strain selection and fermentation**

Isolation and improvement of industrially important strains (Strain improvement: Membrane permeability; Auxotrophic mutants: Analogue resistant mutants; Use of recombination systems). Inoculum development.

Design of fermentation media: Oxygen requirements; Carbon source; Nitrogen source; Precursors; Metabolic regulators to media; Anti-foams,

Sterilization: Thermal death kinetics; Sterilization of medium (Batch and continuous), air and fermentor; Aseptic Sampling.

Microbial growth kinetics: Batch, continuous and fed-batch fermentation.

UNIT II

(16 hrs)

Design and working of a fermentor

Design of fermentor: Criteria for an ideal fermentor; Aseptic Operation and containment; Aeration (Type of Spargers); Agitation; Valves and steam traps; Baffles; Heat exchanger.

Types of fermentors: Tower fermentor; Cylindroconical vessels; Air-lift fermentor; The packed tower; Rotating disc fermentor.

Instrumentation and Control: Methods of measuring process variables such as temperature, agitation, pressure, pH and antifoam. PID control; Use of computers in bioprocess control systems; SCADA Systems for Bioreactors.

UNIT III

(16 hrs)

Downstream processing

Filtration (Batch and continuous); Centrifugation (Basket and bowl centrifugation); Cell disruption (Physical and chemical methods); Liquid-liquid extraction; Supercritical fluid extraction; Membrane filtration (Ultrafiltration, micro-filtration, nano-filtration, reverse osmosis); Crystallization; Drying (Spray, drum and freeze drying)

Production and downstream processing: Penicillin, vitamins -riboflavin, Organic acid- Citric acid.

REFERENCES:

1. Baltz, R. H., Demain, A. L., Davies, J. E., Bull, A. T., Junker, B., Katz, L., Lynd, L. R., Masurekar, P., Reeves, C. D., & Zhao, H. (2010). Manual of Industrial Microbiology and Biotechnology, 3rd ed., Washington DC: ASM Press.
2. Drapcho, C. M., Nghiê, N. P., & Walker, T. H. (2020). Biofuels Engineering Process Technology, 2nd ed., United States of America: McGraw Hill Publications.
3. Gupta, R. B., & Demirbas, A. (2010). Gasoline, diesel, and ethanol biofuels from grasses and plants. United Kingdom: Cambridge University Press.
4. Okafor, N. (2007). Modern Industrial Microbiology and Biotechnology. United States of America: Science Publishers.
5. Richardson, J. F., & Harker J. H. (2002). Coulson and Richardson's Chemical Engineering, 5th ed., Vol 2. United Kingdom: Butterworth- Heinemann.
6. Shuler, M. L., & Kargi, F. (2002). Bioprocess Engineering: Basic Concepts, 2nd ed., United States: Pearson.

7. Singh, R., & Ghosh, S. K. (2004). Industrial biotechnology, New Delhi: Global Vision Publishing House.
8. Stanburry, P. F., Whitaker, A., & Hall, S. (2016). Principles of Fermentation Technology, 2nd ed., United Kingdom: Butterworth Heinemann.
9. Waite, M. J., Morgan, N. L., Rockey, J. S., & Higon, G. (2009). Industrial microbiology: an introduction. Hong Kong: John Wiley & Sons.
10. Young, M. M. (2019). Comprehensive Biotechnology, 3rd ed., United Kingdom: Pergamon Press.

Course Objectives:

This course enables the students to:

- Assimilate the interaction of organisms with one another and the environment, species distribution on earth, and key threats and biodiversity conservation approaches.
- Evaluate the key environmental issues and their consequences.
- Assess the biotechnological solutions to address the negative impacts of microbial processes on materials.
- Comprehend the utilization of microorganisms in wastewater treatment, bioremediation, and biomining.

Course Outcomes:

At the end of the course, a student should be able to:

- Explain and appreciate the concepts of ecology.
- Critically examine biodiversity and human linkages, and appreciate the need for biodiversity conservation and contribute to the developmental pathways and policy framework.
- Relate an environmental issue with its cause and take an initiative in solving them.
- Investigate and develop new biological technologies to mitigate environmental problems.

UNIT I**(16 hrs)****Ecology and Ecosystem**

Atmosphere; Lithosphere; Hydrosphere; Biosphere; Biogeochemical Cycles (Carbon, Nitrogen, Sulphur, Cycling of toxic metals with Lead as an example).

Concepts in ecology: Keystone species; Interspecific interactions; Indicator organisms

Ecosystem ecology: Types of Ecosystem- Terrestrial (Tropical rain forests, Desert, Savanna, Prairies and Tundra); Aquatic (Ocean, Mangroves and Coral reefs). Ecosystem service; Energy flow; Ecosystem connections (Food chain, Food web); Bioaccumulation; Biomagnification.

UNIT II**(16 hrs)****Biodiversity, its threats, and conservation**

Values and types of Biodiversity

Threats to biodiversity: Pollution of air, water and soil, and the control measures. Carbon footprint; Global warming; Climate change.

Conservation: *In-situ* and *Ex-situ* Conservation; Environmental Assessment and Management (Environmental Impact Assessment, Coastal Regulation Zone).

Bioremediation as a sustainable means of biodiversity conservation: Principles of microbial bioremediation, Types (*In-situ*: Intrinsic and engineered, and *ex-situ*: Composting and Vermicomposting, aerated lagoons, low-shear airlift reactors); Microbial degradation of petroleum hydrocarbons and pesticides.

UNIT III

(16 hrs)

Applied Environmental Microbiology

Biodeterioration: Biofouling [Types (Microfouling, Macrofouling), Treatment methods]; Biofilms (Structure, Life cycle, Interactions, Degradation); Microbial Influenced Corrosion (Types) and remedies (Prevention and Treatment).

Biological treatment of liquid wastes: Aerobic systems (Activated sludge process, Trickling filters, Biological filters, Rotating Biological Contractors, Fluidized bed reactor, Expanded bed reactor, Inverse fluidized bed biofilm reactor, Packed bed reactors, Air-sparged reactors); Anaerobic biological treatment (Contact digesters, Packed column reactors, Upflow anaerobic sludge blanket digestion).

Solid waste processing: Bio-methanation of solid waste.

Biomining: Microbial mining of Copper.

REFERENCES:

1. Asthana, D. K., & Asthana, M., (2010). A Textbook of Environmental Studies. New Delhi, S. Chand & Company Ltd.
2. Bhatia, S. C., (2008). Handbook of Environmental Microbiology (Vol. 1, 2 and 3). New Delhi: Atlantic Publishers and Distributors (P) Ltd.
3. De, A. K., (2019). Environmental Chemistry, 9th ed., New Delhi: New Age International (P) Limited.
4. Ghosh, T. K., Chakrabarti, T., & Tripathi G., (2005). Biotechnology in Environmental Management (Vol. I & II). New Delhi: APH.
5. Glazer, A. N., & Nikaido H., (2007). Microbial Biotechnology: Fundamentals of Applied Microbiology, 2nd ed., United Kingdom: Cambridge University Press.

6. Jogdand, S. N., (2015). Environmental Biotechnology, 4th ed., Mumbai: Himalaya Publishing House.
7. Joseph, B., (2017). Environmental Studies, 3rd ed., India: Mcgraw Hill Education.
8. Murugesan, A. G., & Rajakumari, C., (2005). Environmental Science and Biotechnology: Theory and Techniques. Chennai: MJP Publishers.
9. Odum, E. P., & Barrett G. W., (2005). Fundamentals of Ecology, 5th ed., Belmont: Thomson Brooks/ Cole.
10. Tchobanoglous, G., Burton, F. L., Stensel, H. D., Metcalf & Eddy, Inc., & Burton, F. (2005). Waste Water Engineering: Treatment and Reuse, 4th ed., *In* Tchobanoglous, G., Burton, F. L., & Stensel, H. D. (Eds.), McGraw-Hill Education.

Course Objectives:

This course enables the students to:

- Comprehend virus indexing, genetic fidelity testing of micropropagated crops, guidelines for certification and export of tissue culture raised plants.
- Understand the breeding of self, cross pollinated and vegetatively propagated crop plants.
- Appreciate wide hybridization, mutation breeding, seed production and variety development and its conservation.
- Gain comprehensive knowledge regarding certified seed production practices of selected crops such as Hybrid jowar, bajra, potato and maize.

Course Outcomes:

At the end of the course, a student should be able to:

- Demonstrate an understanding of the automation in plant micropropagation.
- Determine the most appropriate method for the breeding of self, cross pollinated and vegetatively propagated crop plants.
- Develop a management plan to eliminate pathogens from plant parts and produce Tissue Culture raised plants with Export potentials.
- Apply various acts and guidelines in production of certified seeds and plant breeding.

Unit I:**(16 hrs)*****In Vitro* Plant Breeding**

Mass multiplication of commercially important crops (any three). Micro propagation in commercial perspectives, advantages, economics, robotics and automation. Virus indexing and genetic fidelity of micropropagated crops. Procedures to eliminate pathogens from plant parts. Certification of Plant Tissue Culture labs, Rules and regulation. Export potentials of Tissue Culture plants.

Unit II:**(16 hrs)****Plant breeding**

Breeding of self and cross pollinated and vegetatively propagated crop plants, Heterosis breeding, Polyploidy and haploids in breeding, Wide hybridization, Mutation breeding,

breeding crops to contain useful and adaptive traits; seed production and variety development and its conservation.

Unit III:

(16 hrs)

Certified seed production practices

Introduction, Indian seeds act, classes of quality seed, requirement for certified seed, seed production and processing. Seed certification. Maintenance of certified seed. Certified seed production of selected crops- Hybrid jowar, bajra, potato and maize.

REFERENCES:

1. Acquah, G., (2012). Principles of Plant Genetics and Breeding, 2nd ed., United States: Wiley-Blackwell.
2. Brown, T. A. (2010). Gene Cloning and DNA Analysis: An Introduction, 6th ed., Oxford: Blackwell.
3. Brown J., Caligari P., & Campus H. (2014). Plant Breeding, 2nd ed., United States: Wiley- Blackwell.
4. Buchanan, B. B., Gruissem, W., & Jones, R. L. (2015). Biochemistry & Molecular Biology of Plants. American Society of Plant Physiologists, United Kingdom: Wiley-Blackwell.
5. Chawla, H. S. (2020). Introduction to Plant Biotechnology, 2nd ed., India: Oxford and IBH Publishing.
6. Glick, B. R., & Pasternak, J. J. (2010). Molecular Biotechnology: Principles and Applications of Recombinant DNA. Washington D.C.: ASM Press.
7. Satyanarayana, B. N., & Varghese, D. B. (2007). Plant tissue culture practices and new experimental protocols, India: IK International Publications.
8. Singh, B.D. (2015). Plant Breeding Principles and methods, New Delhi: Kalyani Publishers
9. Slater, A., Scott, N. W., & Fowler, M. R. (2008). Plant Biotechnology: An Introduction to Genetic Engineering. Oxford: Oxford University Press.
10. Walters, D. R. (2011). Plant Defense: Warding off attack by pathogens, herbivores and parasitic plants, United Kingdom: Wiley-Blackwell Publishing Ltd.

Course Objectives:

This course enables the students to:

- Understand the importance of marine organisms and its biotechnological applications.
- Comprehend the isolation of bioactive compounds from marine bacteria.
- Impart knowledge about spawning, larval rearing, water quality and feeding of commercially important cultivable fin fish, shell fish and ornamental fish.
- Know about the feed formulation technique and their application in aquaculture.

Course Outcomes:

On completion of this course, a student should be able to:

- Comprehend the uses of seaweeds and their products.
- Develop the methods of identification of therapeutic agents from several marine species.
- Understand the marine fish hatchery, Shrimp hatchery and farming techniques.
- Apply biotechnological principles for feed formulation and its manufacturing.

UNIT I**(12 hrs)**

Introduction to biological oceanography: Historical development of biological oceanography, classification of marine environment and marine organisms, properties affecting life in the sea.

Benthic floral components: Seaweeds-classification, occurrence, economic importance, seagrass and saltmarshes-distribution, their role in coastal ecosystems, mangroves-distribution, ecological features, importance and uses of mangroves.

UNIT II**(14 hrs)**

Marine bioactive compounds: Bioactive natural products – anti-bacterial, anti-fungal, anti-viral, anti-inflammatory, anti- tumour, antiparasitic and antihelminthic from macroalgae, marine bacteria, dinoflagellates, coelentrates (corals), bryozoans, sponges and tunicates. Extraction, isolation, purification and characterization of bioactive. Marine drugs, importance and sources, carbohydrates and derivatives, aliphatic acids and derivatives. Antibiotic compounds from marine organisms.

UNIT III

(16 hrs)

Introduction to aquaculture: Commercially important cultivable finfishes, shellfishes and aquatic plants, criteria for selection of candidate species. Culture techniques-monoculture, polyculture-pond, raceway, cages, pens, raft and rope culture. Ornamental fish farming. Seed production technology for edible finfishes, ornamental fishes and shrimp, induced breeding and spawning, larval rearing, water quality, feeding, diseases in larvae and health management.

Aqua feed technology & aquaculture biotechnology: Types of feed, feed formulation, feed ingredients, micro diets, nutritional quality of compounded feeds, culture of live feeds-microalgae, rotifer, Artemia, cladoceran, copepods and polychaetes, nutritional composition of live feeds.

REFERENCES:

1. Castro, P. & Huber M. E. (2003). Marine Biology, New York: McGraw Hill.
2. Chakraborty C., & Sadhu, A. K. (2001). Biology, hatchery and culture technology of tiger prawn and giant freshwater prawn. New Delhi: Daya Publication.
3. Giddings, L., Newman, D. J. (2015). Bioactive Compounds from Marine Extremophiles. New York: Springer International Publishing.
4. Govindan, T. K. (1992). Fish processing Technology, New Delhi: Oxford & IBH Publication.
5. Lalli, C. M., & Parsons, T. R. (1997). Biological Oceanography- An Introduction, Oxford: Elsevier Butterworth-Heinemann.
6. Nicoletti, R., & Vinale, F. (2019). Bioactive Compounds from Marine-Derived *Aspergillus*, *Penicillium*, *Talaromyces* and *Trichoderma* Species. Switzerland: MDPI.
7. Pillai, T. V. R. (2005). Aquaculture principles and practices, Culinary and Hospitality Industry, United States: Wiley.
8. Santhanam, P., Thirunavukkarasu A. R., & Perumal, P. (2015). Advances in Marine and Brackishwater Aquaculture, India: Springer.
9. Venugopal, V. (2008). Marine Products for Healthcare: Functional and Bioactive Nutraceutical Compounds from the Ocean. Boca Raton: CRC Press.

Course Objectives:

This course enables the students to:

- Implement the principle of isolation, growth, maintaining the cultures, techniques of strain improvement.
- Apply the role of micro-organism in production of organic acids, alcohols, wine, vinegar, enzymes, vitamins, antibiotics, amino-acids and steroids.
- Design the criteria for fermentor and operation of bioreactor, submerged and solid-state fermentation for the production of enzymes and therapeutics from biological systems and calculation of yield.
- Analyze the course of downstream processing of proteins including centrifugation, precipitation, dialysis and ion exchange chromatography.

Course Outcomes:

At the end of the course, a student should be able to:

- Execute various selective isolation, replica plating, growth kinetics and the role of various factors affecting the process of microbial growth.
- Purify proteins by using various proteins including centrifugation, precipitation, dialysis and ion exchange chromatography.
- Evaluate different pathways followed in or by the microbes involved in production of these bio-chemicals. Method of manipulating these pathways to get desired yield.
- Demonstrate proficiency in methodologies and equipment employed.

List of Practicals:

1. Isolation and screening of microbes of industrial importance.
2. Biphasic growth of bacteria.
3. Submerged and solid-state fermentation for amylase production.
4. Purification of proteins by ammonium sulphate precipitation.
5. Purification of proteins by dialysis.
6. Purification of proteins by ion exchange chromatography.
7. Cell lysis by ultra-sonication.
8. Cell encapsulation technique and alcohol production.
9. Citric acid production.
10. Estimation of alcohol by CAN.
11. Bioreactor Demonstration of pilot scale.

Course Objectives:

This course enables the students to:

- Relate the theoretical knowledge with practical experiences and experience that practical processes can deviate from theoretically expected behavior.
- Comprehend the interactions of pollutants in water, air, and sub-surface environments.
- Design and execute experiments, and analyze and interpret the outcomes.
- Evaluate environmental pollution problem involving biological and environmental systems.

Course Outcomes:

At the end of the course, a student should be able to:

- Execute scientific collection and preservation of samples.
- Perform the analytical tests aimed at establishing the concentration of pollutants in a water sample.
- Examine the water quality by microbiological tests.
- Demonstrate proficiency in methodologies and equipment employed for the analysis of samples.

List of Practicals:

1. Determination of Total Solids (TS) and Total Dissolved Solids (TDS).
2. Determination of Dissolved Oxygen (DO) and Biological Oxygen Demand (BOD).
3. Determination of Chemical Oxygen Demand (COD).
4. Estimation of Sulphates.
5. Estimation of Phosphates.
6. Determination of Carbon dioxide.
7. Estimation of chlorides.
8. Determination of hardness of water.
9. Microbial analysis of water- MPN, Confirmed and Completed test.
10. Analysis of soil pH, temperature and moisture content.

PS 511.3 P PLANT BREEDING AND SEED TECHNOLOGY PRACTICALS

Course Objectives:

This course enables the students to:

- Understand various methods for the production and preservation of Synthetic seeds and evaluation of seed viability.
- Impart knowledge about different steps and techniques in selfing and crossing.
- Acquire knowledge on various stages of cryopreservation of tissues/embryos.
- Study Genetic analysis of variation in plants.

Course Outcomes:

At the end of the course, a student should be able to:

- Demonstrate various layering, grafting and budding techniques.
- Perform the genetic analysis of variation in plants.
- Design and perform plant hybridization experiments.
- Produce synthetic seeds, perform the cryopreservation and evaluate the viability of the seeds.

List of Practicals:

1. *In vitro* germination studies.
11. Somatic embryo generation.
12. Production and preservation of Synthetic seeds.
13. Haploid culture for development of pure-lines.
14. Selfing and crossing techniques in pollination.
15. Vegetative Plant propagation through
 - a. Layering: (1). Air layering (2). Mound layering
 - b. Grafting
 - c. Budding – T – budding (wild rose and Hibiscus)
7. Plant propagation through Apomixis.
 - a. Polyembryony – Mango seedlings
 - b. Vivipary - Alpinia and grass
8. Cryopreservation and regeneration of embryos.
9. Genetic analysis of variation in plants.
10. Excursion to research institutes engaged in plant breeding.

Course Objectives:

This course enables the students to:

- Understand the identification and the industrial application of commercially valuable seaweeds and marine bacteria.
- Impart knowledge about mangroves and its species identification.
- Understand pawning, larval rearing, water quality and feeding of commercially important cultivable fin fish, shell fish and ornamental fish.
- Learn the techniques of construction of glass aquarium.

Course Outcomes:

On completion of this course, students should be able to:

- Appreciate the techniques and applications of fisheries and aquaculture.
- Identify therapeutic agents from marine species.
- Contribute to feed formulation and its manufacturing.
- Demonstrate the ability to become an entrepreneur in ornamental fish farming.

List of Experiments:

1. Phytoplankton- identification of common forms.
2. Estimation of Chlorophyll 'a' concentration.
3. Seaweeds-identification of commercially valuable groups.
4. Mangroves-identification of common species.
5. Finfishes-identification of common food species.
6. Identification of cultivable shrimp and prawns.
7. Visit to Marine and Fisheries Institutes.
8. Industrial visit to fish hatchery and grow-out farm.
9. Industrial visit to ornamental fish farm.
10. Techniques of construction of glass aquarium and its maintenance.

Course Objectives:

This course enables the students to:

- Comprehend GLP, GMP and ethical issues in biological research.
- Understand ethical aspects related to animal experimentation, animal rights, various *in vitro* and *in silico* model in preclinical research.
- Gain knowledge regarding ICH-GCP, phases in clinical trial, bioethics in clinical research.
- Comprehend intellectual property rights, procedure for granting a patent, and their implications in biological research and product development.

Course Outcomes:

At the end of the course, a student should be able to:

- Demonstrate an understanding of the steps involved in the drug discovery and design process.
- Demonstrate an understanding of the importance of strict quality control and regulation in the drug development process, and an awareness of GMP, GLP and GDoP.
- Design and manage various essential documents for the conduct of a clinical trial.
- Apply intellectual property law principles (including copyright, patents, designs and trademarks) to real problems and analyze the social impact of intellectual property law and policy.

UNIT I:**(16 hrs)****Preclinical Studies**

Overview of Drug discovery process, Preclinical trials: various *in vitro*, and animal models in drug development, an insight into Good Laboratory Practices for Preclinical Studies and CPCSEA guidelines for animal studies. Pharmacodynamics (ADME) & Pharmacokinetics, toxicology (LD 50, ED 50), stability studies- drug formulation.

UNIT II:**(16 hrs)****Clinical Research**

History of Regulations in Clinical Research. Good Clinical Practices (GCP), Principles of ICH -GCP. Key Stakeholders in Clinical Research (brief the responsibilities of - Ethics Committees and Institutional Review Board, Sponsor, Investigator and the monitor). Types of Clinical Research, Phases of clinical trials, Informed Consent Form, Case Report Form, Investigator's Brochure.

UNIT III:

(16 Hrs)

Introduction to Intellectual Property and Patents

Intellectual Property Rights, Legislature regulating IPRs in India. International patenting- Patent cooperation treaty (PCT), World Intellectual Property Organization (WIPO). Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Introduction to US patent system.

Patents: Patent system in India, Invention & conditions for patenting an invention, Types of patent applications -Ordinary Application, Application for Patent of Addition, Convention application, National Phase Application under PCT & PCT International Application, Divisional Application, filing of patent application, Revocation of patent in India. Bio piracy. Copyright, Trademarks, Trade secrets, Geographical indications, Industrial designs.

REFERENCES:

1. Acharya, N. K. (2014). Text book of intellectual property rights, 7th ed., Hyderabad: Asia Law House.
2. Ashok, K. M., & Mohd, I. A. (2008). Intellectual property rights, 1st ed., New Delhi: Serials Publications.
3. Daan, J. A., Robert D. S., & Meibohm B. (2013). Pharmaceutical Biotechnology- Fundamentals and Applications, 4th ed., New York: Springer.
4. Duolao, W., Ameet, B. & Remedica., (2006). Clinical Trials: A Practical Guide to Design, Analysis, and Reporting, United Kingdom: Remedica
5. Gopalakrishnan, N. S., & Agitha, T. G. (2009). Principles of Intellectual Property, Lucknow: Eastern Book Company.
6. Gupta, S. K. (2011). Drug Discovery and Clinical Research, Jaypee Brothers, New Delhi: Medical Publishers Pvt. Ltd.
7. Kuhse, H., & Singer, P. (2010). Bioethics: An anthology, United States of America: Wiley Blackwell.

8. Lawrence, M. F., Curt D. F., & David, L. D. (2010). Fundamentals of clinical trials, New York: Springer-Verlag.
9. Rick, N. G. (2004). Drugs from discovery to approval, New Jersey: Wiley-Liss Publication.
10. Tom, B. (2016). Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines, 2nd ed., Massachusetts: Academic Press.

Course Objectives:

This course enables the students to:

- Appreciate the substitution of the conventional treatment methods with modern biotechnology approaches.
- Illustrate the diverse role that a range of biological systems play in the clean-up of compounds that are either accidentally or deliberately released into the environment.
- Identify the pollutants of greatest concern, describe the principles of various bioremediation techniques and relate selection of these techniques to the properties of the contaminants.
- Describe how systems can be successfully engineered to support/ promote remediation with an emphasis on bioremediation.

Course Outcomes:

At the end of the course, a student should be able to:

- Describe the concept and applications of bioremediation.
- Evaluate the manipulation of prokaryotic and eukaryotic cells in culture, and to apply specific cellular and molecular techniques.
- Appraise when each bioremediation strategy would be most applicable, based on the polluted site characteristics.
- Develop a new and suitable technique to clean-up the environmental contaminants using the knowledge in bioremediation techniques.

UNIT I**(16 hrs)****Introduction to Bioremediation**

Case histories; Introduction to Bioremediation; Concepts in bioremediation: Xenobiotic Compounds, Recalcitrance, Bioaugmentation, Biostimulation; Constraints and priorities of bioremediation; Factors affecting bioremediation; Factors affecting microbial activity (Choice of electron acceptor, toxicity of pollutant, C/N/P ratio, co-substrates, soil humidity, pH and temperature); Types of Bioremediation (*In-situ* and *ex-situ*).

UNIT II**(16 hrs)****Bioremediation techniques**

Biosorption; Biofilters; Biotransformation; Biodegradation; Bioremediation using Genetically Engineered Microbes (GEM); Phytoremediation (Bioavailability of pollutant, plant biology of pollutant accumulation, naturally occurring plants for Phytoremediation, transgenic plants for Phytoremediation); Rhizoremediation; Microalgal biotechnology in biological removal of nutrients.

UNIT III

(16 hrs)

Application of bioremediation techniques for Pollution Control

Solid phase bioremediation: Land farming, prepared beds, soil piles, composting, bioventing, and biosparging. Phytoremediation in wastewater treatment using aquatic plants and root zone treatment.

Liquid phase bioremediation: Suspended bioreactors, fixed biofilm reactors.

GEM for treating oil spills, GEM for sequestering of heavy metals; Biotransformation of heavy metals; Biodegradation of xenobiotics.

REFERENCES:

- 1) Alexander, M., (1999). Biodegradation and Bioremediation, 2nd ed., USA: Academic Press.
- 2) Baker, K. H., & Herson, D. S., (1994). Bioremediation. New York: McGraw-Hill Professional.
- 3) Crawford, R. L., & Crawford, D. L., (1996). Bioremediation: Principles and Applications. UK: Cambridge University Press.
- 4) Ergas, S. J., Chang, D. P. Y., Shroeder, E. D., & Eweis, J. B., (1998). Bioremediation principles. USA: William C Brown Pub.
- 5) Jogdand, S. N., (2015). Environmental Biotechnology, 4th ed., Mumbai: Himalaya Publishing House.
- 6) Norris, R. D., (1994). Handbook of Bioremediation, 1st ed., Boca Raton: CRC Press.
- 7) Rajendran, P., & Gunasekaran, P., (2019). Microbial bioremediation. Chennai: MJP Publishers.
- 8) Rathoure, A. K., (2017). Bioremediation: Current Research and Application. Bangalore: I K International Publishing House Pvt. Ltd.
- 9) Sangeetha, J., Thangadurai, D., David, M., & Abdullah, M. A., (2017). Environmental Biotechnology: Biodegradation, Bioremediation, and Bioconversion of Xenobiotics for Sustainable Developments. USA: Apple Academic Press.
- 10) Singh, A., & Ward O., (2004). Biodegradation and Bioremediation. Springer.

FOURTH SEMESTER

PH 501.4

FOOD BIOTECHNOLOGY

Hours: 56

Course Objectives:

This course enables the students to:

- Understand the regulatory aspects of food biotechnology.
- Acquire knowledge on the role of microbes in food production and food spoilage.
- Understand the basic principles of preservation techniques and the unit operations employed in a food processing plant.
- Gain in-depth understanding of biotechnology of fermented foods.

Course Outcomes:

On completion of the course, a student should be able to:

- Explain the importance of food laws, acts, quality control and sensory evaluations.
- Describe the factors affecting growth of microorganisms.
- Apply the knowledge of processing and preservation techniques in increasing the shelf life of food products.
- Produce different oriental and traditional fermented foods.

UNIT I

(14 hrs)

Food Quality & Regulations

Concepts of food quality: Physical, chemical, nutritional, microbial and sensory, Food adulteration, Quality assessment of food materials. Grades and standards, Food regulations: FSSAI, Concept of Codex Alimentarius, USFDA, ISO 22000/ HACCP. Nutraceuticals, prebiotics and probiotics in human diet, Neutragenomics, Fecal transplants.

UNIT II

(14 hrs)

Food Microbiology

Food spoilage mechanisms (in milk, meat, canned food), Types of micro- organisms normally associated with food – moulds, yeast and bacteria and their control in food stuffs (vegetables, cereals, pulses, oilseeds, milk and meat during handling and processing). Biochemical changes in food (rancidity, enzymic browning, nutritional changes, flavor changes, Maillard reactions). Mechanism of action of exotoxins (enterotoxins) and endotoxins. Microbial food poisoning.

UNIT III

(14 hrs)

Principles and methods of food preservation

Natural preservatives, heating (blanching, pasteurization, sterilization and UTH processing, dielectric heating, microwave heating, baking, roasting and frying), dehydration, minimal processing, canning, irradiation, Processing using low temperature- refrigeration, freezing, smoking and pickling. Preservation of volatiles, Food additives: definition, types and functions, permissible limits and safety aspects.

UNIT IV

(14 hrs)

Food fermentations and Importance of Microbial biomass

Microbial beverages: Production of wine and beer.

Fermentation of Milk products – production of cheese- Swiss & Cheddar.

Oriental food: miso, tempeh, soya sauce, idli.

Microbial biomass as food: Baker's yeast, SCP, Mushroom cultivation.

Microbial exopolysaccharides: uses of cyclodextrin, chitosan, pullulan, dextran, gellan, xanthan gum in food industry.

REFERENCES:

1. Demain, A., & Davis, J. E. (2010). Manual of Industrial Microbiology & biotechnology, 3rd ed., Washington DC: ASM Press.
2. Fennema, O. R. (2006). Food chemistry, 3rd ed., New York: Marcel Dekker Inc.
3. Jay, J. M., Loessner, M. J. & Golden, D.A., (2006). Modern Food Microbiology 7th ed., New York: Springer Science and Business Media, Inc.
4. Johnson-Green, P. (2018). Introduction to Food Biotechnology, New York: CRC Press.
5. Knorr, D. (2005). Food Biotechnology, New York: Marcel Dekker Inc.
6. Lee, B. H. (2015). Fundamentals of Food Biotechnology, 2nd ed., United Kingdom: Wiley-Blackwell Publishers.
7. Levin, R. E. (2006). Food Biotechnology, 2nd ed., United States of America: Taylor and Francis.
8. Nollet, L. M. L. (2015). Handbook of food analysis, 3rd ed., Boca Raton: CRC press.
9. Young, M. M. (2019). Comprehensive Biotechnology, 3rd ed., United Kingdom: Pergamon Press.
10. Prescott, S. C., & Dunn, C. G. (2004). Industrial Microbiology, 4th ed., Australia: McGraw Hill Book Publishers.

PH 502.4 MOLECULAR DIAGNOSTICS AND IMMUNOTECHNIQUES

Hours: 56

Course Objectives:

This course enables the students to:

- Acquire in-depth knowledge in PCR based molecular diagnosis of infectious diseases.
- Sensitize students about recent advances in biomarkers in disease diagnostics.
- Provide a thorough understanding of the various immunotechniques.
- Teach students with a deep insight about monoclonal antibody production and antibody engineering.

Course Outcomes:

On completion of this course, students should be able to:

- Design PCR based diagnostic method for infectious diseases.
- Understand genomics, proteomics and metabolomics that could be employed in early diagnosis and prognosis of human diseases.
- Execute this knowledge in the processes of antibody engineering, vaccine development, immunization and cancer therapy.
- Apply techniques of molecular biology/immunology in research work/pharma industries and other relevant biotech industries.

UNIT I

(14 hrs)

PCR in molecular diagnostics

Introduction and History of diagnostics. Biosafety for Specimen Handling, Infectious disease specimen collection, transport and processing of specimen, Viral Transport Medium (VTM). Real Time PCR-based molecular diagnosis of infectious disease: Covid 19, H1N1. Nested PCR in typing of dengue viruses, PCR in forensic science- AmpFLP, STR. Multiplex PCR for respiratory pathogens/ foodborne pathogens. Determination of Paternity- Human identification and sex determination.

UNIT II

(14 hrs)

Biomarkers in disease diagnostics

Diagnostic metabolomics- Metabolite profile for biomarker detection in the body fluids/tissues using LCMS & NMR. Molecular oncology: Detection of recognized genetic aberrations in clinical samples from cancer patients- Anaplastic Lymphoma Kinase (ALK) rearrangement detection with immunohistochemistry (IHC), Germline/somatic BRCA 1/2 mutation detection with DNA sequencing. NGS-based diagnostic cancer assays. Predictive biomarkers for personalized onco-therapy of human diseases such as chronic myeloid leukemia and breast. Detection of inherited diseases- Fragile X Syndrome, von-Hippel Lindau disease.

UNIT III

(14 hrs)

Immunoassay Techniques

Radioimmunoassay: ELISA, RIA, Immunofluorescence, comet assay, ELISPOT assay; Western blot, FACS. Surface plasmon resonance (SPR), Biosensor assays for assessing ligand – receptor interaction, Staining techniques for live cell imaging and fixed cells; non isotopic methods of detection of antigens – enhanced chemiluminescence assay; Cell Functional Assays – lymphoproliferation, Cell Cytotoxicity, mixed lymphocyte reaction, Cytokine expression; Cell imaging Techniques- In vitro and In vivo.

UNIT IV

(14 hrs)

Antibody engineering and vaccine technology

Monoclonal antibodies. Polyclonal antibodies vs. monoclonal antibodies. Applications of monoclonal antibodies. Antibody engineering: Antibody Cloning, Antibody library screening- Phage display technique and its applications. Therapeutic antibodies, Catalytic antibodies.

Rationale of vaccine design: types of vaccines: live, killed, attenuated, Sub unit vaccines; Recombinant DNA and protein-based vaccines; Peptide vaccines, conjugate vaccines; mRNA vaccine and viral vector vaccine. Passive Immunization; Antibody, Transfusion of immuno-competent cells, Plasma therapy

REFERENCES:

1. Abbas, A., Lichtman, A. H., & Pillai, S. (2017). Cellular and Molecular Immunology, 9th ed., Philadelphia: Elsevier.
2. Brooker, R. J., (2009). Genetics: Analysis & Principles. New York: McGraw-Hill.

3. Coleman, W. B., & Tsongalis, G. J. (2010). *Molecular Diagnostics: for the Clinical Laboratorian*. Totowa, New Jersey: Humana Press.
4. Delves, P. J., Martin, S. J., Burton, D. R., & Roitt, I. M. (2017). *Roitt's Essential Immunology*, 13th ed., United Kingdom: Wiley- Blackwell.
5. Glick, B. R., Pasternak, J. J., & Patten, C. L. (2010). *Molecular Biotechnology: Principles and Applications of Recombinant DNA*. Washington DC: ASM Press.
6. Male, D., Brostoff, J., Roth, D. B. & Roitt, I. V. (2012). *Immunology*, 8th ed., United States: Elsevier Saunders.
7. Owen, J., Jenni P. J., & Stranford, S. (2018). *Kuby Immunology*, 8th ed., New York: W. H. Freeman.
8. Stephenson, J. R., & Warnes, A. (1998). *Diagnostic Virology Protocols (Methods in Molecular Medicine)*. 1st ed., New Jersey: Humana Press.
9. Talwar G. P., & Gupta S. K. (1992). *A hand book of practical and clinical immunology*, Vol. 1 & 2, India: CBS Publications.
10. White, L. D. & Wong, L. C. (2013). *Next Generation Sequencing: Translation to Clinical Diagnostics*. 1st ed., New York: Springer-Verlag.

PH 503.4 PROJECT DISSERTATION/ INTERNSHIP REPORT AND VIVA VOCE

Scheme for Project in the IV semester

Project dissertation and *viva voce*

Marks- 100

Project work is *in lieu* of one practical in the IV th semester and shall be carried out by the student or a group of maximum three students under the guidance of a research supervisor. A synopsis of the work is to be submitted which is evaluated by internal committee which comprise all staff, suggestions if any is incorporated and sent to the external evaluator to come prepared for the *Viva voce* (at least 1 week in advance).

The thesis/ dissertation is to be typed and bound with bonafide certificate and submitted during practical exam for valuation

Internal assessment

30 marks

- Presentation of the work done before the internal committee 10 marks
- Continuous assessment awarded by guide 20 marks

(Criteria for continuous assessment is regular submission of reports of the literature review, work done, interpretation of results and overall progress of the project work)

End semester examination:

Project Dissertation and *viva voce*

70 marks

- Thesis/ Industry Internship Report 45 marks
- Presentation 15 marks
- *Viva voce* 10 marks

Course Objectives:

This course enables the students to:

- Utilize laboratory techniques to enumerate the microorganisms in food.
- Acquire skills on various methods of assessing food quality.
- Understand the various tests to detect adulterants in various food samples.
- Acquire in-depth knowledge on the methodology of production of fermented beverage.

Course Outcomes:

On completion of the course students will be able to:

- Explain the different microorganisms associated with food and evaluate the microbial estimation in food.
- Identify and control adulterants in various foods and evaluate food quality.
- Apply the technique of growing mushrooms as an alternative food product.
- Comprehend the knowledge of wine production and launch a startup.

List of Practicals:

1. Determination of acidity in Curd / Milk –by titration method.
2. Methylene blue dye reduction test.
3. Resazurin test.
4. Turbidity test.
5. Direct Microscopic Count.
6. Detection of adulterants in Fats and oils/ Milk/other foods.
7. Lab scale production of alcoholic beverages (Wine).
8. Determination of total acidity of wine.
9. Estimation of alcohol by specific gravity method.
10. Colorimetric estimation of ethanol.

PH 505.4P MOLECULAR DIAGNOSTICS AND IMMUNOTECHNIQUES
PRACTICALS

Course Objectives:

This course enables the students to:

- Apply PCR for amplification of a gene of interest.
- Understand the application of Nested PCR in detection of a microorganism.
- Comprehend various antigen-antibody reactions.
- Acquire in-depth knowledge in immunotechniques.

Course Outcomes:

At the end of the course, a student should be able to:

- Design and conduct PCR based experiments for disease diagnostics.
- Perform nested PCR experiments for identification of a microorganism.
- Demonstrate Real Time PCR.
- Perform various immunotechniques like ELISA, western blotting.

List of Practicals:

1. Differential count of WBCs.
2. Antigen-Antibody reactions.
3. Ouchterlony Immunodiffusion.
4. ELISA for quantification of an antigen.
5. Comet assay/ELISPOT assay.
6. Immunoelectrophoresis.
7. Western blotting.
8. Nested PCR for detection and typing of dengue viruses.
9. PCR based detection of microorganisms.
10. Real Time PCR analysis (Demo).

Course Objectives:

This course enables the students to:

- Learn GLP, GMP and ethical issues in biological research.
- Understand ethical aspects related to animal experimentation, animal rights, various *in vitro* and *in silico* model in preclinical research.
- Gain knowledge regarding ICH-GCP, phases in clinical trial, bioethics in clinical research.
- Comprehend intellectual property rights, procedure for granting a patent, and their implications in biological research and product development.

Course Outcomes:

At the end of the course, a student should be able to:

- Demonstrate an understanding of the steps involved in the drug discovery and design process.
- Demonstrate an understanding of the importance of strict quality control and regulation in the drug development process, and an awareness of GMP, GLP and GDoP.
- Design and manage various essential documents for the conduct of a clinical trial.
- Apply intellectual property law principles (including copyright, patents, designs and trademarks) to real problems and analyze the social impact of intellectual property law and policy.

UNIT I:**(16 Hrs)****Drug discovery and Preclinical studies**

Different phases in drug development, Preclinical trials: various *in vitro*, and animal models in drug development, pharmacology (Pharmacodynamics & Pharmacokinetics), Dose Response Curve, Efficacy and Toxicity(LD 50, ED 50), and stability studies- drug formulation. An insight into Good Laboratory Practices for Preclinical Studies and CPCSEA guidelines for animal experimentation. Overview of Good Manufacturing Practices and good documentation practices in drug manufacturing.

UNIT II:**(16 Hrs)**

Clinical Research

Scope of Clinical Research, Good Clinical Practices (GCP), Historical guidelines in Clinical Research- Nuremberg Code, Kefauver Amendments, Declaration of Helsinki, and Belmont report. Overview of regulation in clinical research (US –FDA and Schedule Y). Principles of ICH –GCP. Types of clinical research, phases of clinical trials, key stakeholders in clinical research (brief the responsibilities of - Ethics Committees and Institutional Review Board, sponsor, investigator and the monitor).

Randomized control trial and blinding. Investigator's Brochure (IB), Informed consent form, Case Report Form. Role of CRA, QA and QC in Clinical Trials.

UNIT III:

(16 Hrs)

IPR and Patents

Intellectual Property Rights, Legislature regulating IPRs in India. International patenting- Patent cooperation treaty (PCT), World Intellectual Property Organization (WIPO). Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Introduction to US patent system.

Patents: Patent system in India, Patent offices, Invention & conditions for patenting an invention, e-Notebook and Documentation .Types of patent applications-Ordinary Application, Application for Patent of Addition, Convention application, National Phase Application under PCT &PCT. International Application, Divisional Application, filing of patent application, Revocation of patent in India, Biopiracy, Copyright, Trademarks, Trade secrets, Geographical indications, Industrial designs, Protection of Plant Varieties, Registration of new plant variety.

REFERENCES:

1. Acharya, N. K. (2014). Text book of intellectual property rights, 7th ed., Hyderabad: Asia Law House.
2. Ashok, K. M., & Mohd, I. A. (2008). Intellectual property rights, 1st ed., New Delhi: Serials Publications.
3. Daan, J. A., Robert D. S., & Meibohm B. (2013). Pharmaceutical Biotechnology- Fundamentals and Applications, 4th ed., New York: Springer.
4. Duolao, W., Ameet, B. & Remedica., (2006). Clinical Trials: A Practical Guide to Design, Analysis, and Reporting, United Kingdom: Remedica

5. Gopalakrishnan, N. S., & Agitha, T. G. (2009). Principles of Intellectual Property, Lucknow: Eastern Book Company.
6. Gupta, S. K. (2011). Drug Discovery and Clinical Research, Jaypee Brothers, New Delhi: Medical Publishers Pvt. Ltd.
7. Kuhse, H., & Singer, P. (2010). Bioethics: An anthology, United States of America: Wiley Blackwell.
8. Lawrence, M. F., Curt D. F., & David, L. D. (2010). Fundamentals of clinical trials, New York: Springer-Verlag.
9. Rick, N. G. (2004). Drugs from discovery to approval, New Jersey: Wiley-Liss Publication.
10. Tom, B. (2016). Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines, 2nd ed., Massachusetts: Academic Press.

PS 507.4 STEM CELL TECHNOLOGY AND REGENERATIVE MEDICINE

Hours: 48

Course Objectives:

This course enables the students to:

- Comprehend different types of stem cells.
- Understand how to identify and isolate stem cells for various research purposes.
- Familiarize the stem cell technology and its applications for betterment of the society.
- Understand different therapeutic areas that can benefit with pluripotent stem cell-based cell replacement therapies.

Course Outcomes:

On completion of this course, students should be able to:

- Demonstrate knowledge of different types of stem cells and their specific characteristics, sources of stem cells, their isolation and characterization.
- Understand the clinical need for stem cell therapy and tissue engineering in regenerative medicine.
- Understand the innovation and technological progress of stem cell research in recent years.
- Lead a professional career in stem cell technology and cell/tissue engineering in a wide range of health care establishments.

Unit I (16 hrs)

The Biology of Stem Cells

Different types of stem cells – embryonic stem cells, fetal tissue stem cells, adult stem cells; stem cell differentiation, stem cell plasticity – Differentiation versus stem cell renewal. Isolation and propagation of embryonic stem cells; chimeras; generation of knockout mice and knock-in technology.

Unit II (16 hrs)

Bone Marrow Transplantation

Hematopoietic stem cells and bone marrow transplantation: Cells for hematopoietic reconstitution – Cord blood stem cells; cells for adoptive cellular immunotherapy; bone marrow transplantation - advantages and disadvantages.

Unit III

(16 hrs)

Regenerative Therapy

Introduction, Current stem cell therapies. Hematopoietic Stem Cell in the treatment of Cancer. Stem cell therapy for regeneration in muscular dystrophy, inter-vertebral disc degeneration, cerebral infarcts and transplantation medicine, Repair of damaged organs such as the liver and pancreas. Engineered Tissues and Regenerative Medicine. Personalized therapies in Regenerative Medicine

REFERENCES:

1. Atala, A., (2009). Foundations of Regenerative Medicine: Clinical and Therapeutic Applications, 1st ed., United States: Academic Press.
2. Atala, A., & Thomson, J.A., (2007). Principles of Regenerative Medicine, 1st ed., United States: Academic Press.
3. Freshney, I. (2005). Culture of Animal Cells, 5th ed., United States: Wiley Publishers.
4. Steinhoff, G. (2011). Regenerative Medicine, 1st ed., Germany: Springer.
5. Baharvand, H., & Aghdami, N. (2013). Regenerative Medicine and Cell Therapy New York: Humana Press.
6. Ann Kiessling, A., & Anderson, S. C. (2006). Human Embryonic Stem cells, 2nd ed., United States of America: Jones & Barlett Publishers.
7. Lanza, R., & Atala, A. (2005). Essentials of Stem Cell Biology, United States of America: Academic Press.
8. Slack, J. M. W. (2018). The Science of Stem Cells. 1st ed., United States of America: Wiley Blackwell.
9. Stocum, D.L., (2012). Regenerative Biology and Medicine, 2nd ed., United States of America: Academic Press.
10. Turksen, K., (2004). Adult Stem Cells, Humana Press, Inc. Handbook of Stem Cells: Embryonic/ Adult and Fetal Stem cells (Vol. 1 & 2), United States of America: Academic Press.

Course Objectives:

This course enables the students to:

- Develop awareness about the biotechnology enterprise.
- Understand the principles of human resource management and marketing.
- Gain insights into establishment of innovative startups.
- Get exposure to the global scenario of biotechnology industries.

Student Learning Outcomes:

At the end of the course, a student should be able to:

- Prepare business plan for biotechnology entrepreneurship.
- Address the market challenges for a new enterprise.
- Assess the global market scenario of their product.
- Manage technology transfer for new biotechnology product and launch a startup.

Unit I**(14 hours)****Concept of Bio-entrepreneurship**

Traditional entrepreneurship versus Bio-entrepreneurship. Risk and benefit, Steps involved in commercialization of a biotechnological product. Types of bio-industries – bio services bio industrial, agribio and biopharma; business incubators. Entrepreneur, types of entrepreneur, development of entrepreneurship, stages in entrepreneurial process, role of entrepreneurs in economic development, entrepreneurship - its barriers.

Principles of management:

Introduction, definition –principles and decisions on starting a venture; sources of financial assistance – making a business proposal, approaching loan from bank and other financial institutions, budget planning and cash flow management, basics in accounting practices - balance sheet, P&L account, and double entry book keeping; estimation of income, expenditure, profit, income tax etc.

Unit II Human Resource Development and marketing:**(14 hours)**

Recruitment and selection process; leadership skills; managerial skills; organization structure; training; team building; teamwork; Appraisals and rewards. Marketing: Assessment of market demand for potential product(s) of interest; Market conditions, segments; prediction of market changes; identifying needs of customers including gaps in the market. Market

linkages, branding issues; Developing distribution channels; Pricing/Policies/Competition; Promotion/Advertising; Services Marketing, Opportunities and lessons in international marketing.

Unit III

(14 hours)

Innovation and Start-up

Innovation – types, out of box thinking, R&D for technology development and up-gradation; assessment of technology development. Knowledge centres like universities and research institutions; Managing Technology Transfer, Regulations for transfer of foreign technologies; Technology transfer agencies.

Start-up: Setting of a small industry, location of an enterprise, steps of starting small industry, Incentive & subsidies for industry, The Art of Negotiation, Workable marketing and the strength of distribution. Support mechanism for entrepreneurship in India - agencies like MSME/banks and private agencies like venture capitalists. Statutory and legal requirements for starting a company/venture. Use of IT for business administration; Use of IT in improving business performance; Available software for better financial management; E-business setup, management.

REFERENCES:

1. Adams, D. J., & Sparrow, J. C. (2008). Enterprise for life scientists: Developing innovation and entrepreneurship in the biosciences. Bloxham: Scion.
2. Desai, V., (2009). The Dynamics of Entrepreneurial Development and Management. New Delhi: Himalaya Pub. House
3. Hisrich, R. D., Peters M. P., & Shepherd, D. A. (2017). Entrepreneurship. 10th ed., United States: McGraw-Hill Education.
4. Hine, D., Kapeleris, J., & Elgar, E. (2006). Innovation and Entrepreneurship in Biotechnology, An International Perspective- Concepts, Theories and Cases, Cheltenham: Edward Elgar Publishing.
5. Jogdand, S. N. (2007). Entrepreneurship and Business of Biotechnology, India: Himalaya Publication House.
6. Jordan, J. F. (2014). Innovation, Commercialization, and Start-Ups in Life Sciences, London: CRC Press.
7. Mehta, S. S. (2008). Commercializing Successful Biomedical Technologies, United Kingdom: Cambridge University Press.

8. Onetti, A., & Zucchella, A. (2014). Business modeling for life science and biotech companies: Creating value and competitive advantage with the milestone bridge. New York: Routledge.
9. Patzelt, H., & Thomas, B. (2008). Handbook of Bioentrepreneurship, New York: Springer.
10. Shimasaki, C. D. (2014). Biotechnology entrepreneurship: Starting, managing, and leading biotech companies. Amsterdam: Elsevier.

Model Question Paper

Paper Code

Reg. No:

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St Aloysius College (Autonomous), Mangaluru

**Semester I – P.G. Examination – M.Sc. Biotechnology
January – 2022
Biochemistry**

Time: 3Hours

Max. Marks: 70

Note: Draw neat labeled diagrams/schematic sketches/structures wherever necessary.

I. Write short notes on any FIVE of the following. (5x3 = 15)

1. Define mutarotation with explain with an example
2. Comment on sphingolipids
3. Brief about peptide bonds
4. Give an account on Chargaff's rule
5. Write a note on regulation of blood sugar
6. Briefly comment on inhibitors of ETS
7. Give an account on transamination
8. What is mean by alpha oxidation? Narrate with an example

II. Write explanatory notes on any FIVE of the following. (5x5 = 25)

9. Explain structure and functions of starch and glycogen
10. Discuss on phospholipids
11. Give an account on t-RNA
12. Describe the structure of hemoglobin
13. Explain gluconeogenesis
14. Explain mitochondrial components and complexes for ATP synthesis
15. Give an detailed account on biosynthesis of lipids
16. Discuss on ketone bodies

III. Answer any THREE of the following. (3x10=30)

17. Explain on lipoproteins
18. Discuss on secondary and tertiary structures of protein

19. Explain classification of amino acids
20. Describe pentose phosphate pathway with its regulation and significance
21. Explain salvage pathways for purine and pyrimidine metabolism

Theory Internal Assessment:

Two internal examinations will be conducted during every semester at the end of 6th week and 12th week. A third improvement examination will be held for the students who desire to improve their earlier performance or for those who have missed the earlier internal examination.

Duration of the examination: 1 ½ hrs

Total marks: 50

I. Section A

1-7: Answer any **5 out of 7** short/analytical-type question

3 × 5 = 15

II. Section B

8 to 13: Answer any **4 out of 6** questions of short answer type in about 250 words. Each answer carries 5 marks.

5 × 4 = 20

III. Section C

14 to 16: Answer any **1 out of 3** questions of long answer / essay type

Each answer carries 15 marks

15 × 1 = 15

50% of internal assessment will be based on continuous evaluation (based on presentation/ quizzes/ assignments/ class participation/ surprise tests).

Continuous Internal Assessment (CIA)	
Two Internal tests 50 marks each	25
Seminars/Quiz/Surprise Tests	12
Assignments/Review/report writing	10
Class Participation	3
Total	50 Marks

Distribution of marks for class participation:

≥91 %	: 3
≥85 – 90 %	: 2
≥76 – 84 %	: 1

Practical internal assessment

Internal practical examination marks will be based **on a model practical examination** conducted after completion of all the practical of the concerned semester.

Continuous assessment will be based on marks allotted for class participation and regular submission of practical record

Model Practical test

15 marks

END SEMESTER EXAMINATIONS

Theory: Duration of the examination: 3 hours

Total marks:70

Every Section of the question paper should include questions from all the units of the syllabus.

I. Five questions of **short answer type** (eg. Enumerative/Analytical/Definition)
(Five out of eight)

Question no 1-8. Each answer carries **3** marks

$3 \times 5 = 15$

II. Five questions. Explanatory type (Five out of eight)

Question no 9-16 (At least 1 question from each unit, not more than 2 questions from each unit) Each answer carries **5** marks

$5 \times 5 = 25$

III. Three questions of long answer / essay type (Three out of five)

Question no 17-21 (At least one question from each unit, not more than two questions from each unit)

Each answer carries **10** marks

$10 \times 3 = 30$

End Semester Practical Exam	Duration: 4 hours	Marks: 35
1. Major experiment		10
2. Minor experiment		20
3. Spotters A and B (analytical problem/procedure writing)		05
4. Class record		05
5. VIVA		10
