St Aloysius College (Deemed to be University) Mangaluru

Course structure and Syllabus of

M.Sc. Biotechnology

CHOICE BASED CREDIT SYSTEM (CBCS)

(2024 –25 BATCH ONWARDS)

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 and critically think about the concepts in Biotechnology.

PSO 3: Ability to work independently, while still promoting team work and collaboration skills.

PSO 4: Execute their professional roles in society as biotechnology professionals, employers and employees in various industries, regulators, researchers, educators and managers.

PSO 5: Demonstration of integrity, honesty, ethical behaviour and sense of responsibility.

PSO 6: Appreciation of diversity in scientific community and responsibility towards society and nation.

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 SWAYAM and NPTEL.

DEPARTMENT OF PG STUDIES AND RESEARCH IN

BIOTECHNOLOGY UNDER NEP

Scheme and Syllabus for M.Sc. Biotechnology 2024-25

FIRST SEMESTER

Course Code	Course Title	Teaching hours per week	Credits	Duration of exam In hours	Marks		Total
					Internal Assessment	End sem. Exam	
PH501.1	Biochemistry and Metabolism	4	4	3	40	60	100
PH502.1	Microbiology	4	4	3	40	60	100
PH 503.2	Food Biotechnology	4	4	3	40	60	100
PH 504.1 P	Biochemistry and Analytical Techniques	4	2	3	20	30	50
PH 505.1P	Microbiology+ Food Biotechnology	4	2	3	20	30	50
PS 506.1	Molecular Genetics	3	3	3	40	60	100
PS 507.1	Research Methodology, Ethics and Scientific Communication	3	3	3	40	60	100
PS 508.1P	Molecular Genetics	4	2	3	20	30	50
Total			**24**	**;**			**650**

SECOND SEMESTER

Course Code	Course Title	Teaching hours per week	Credits	Duration of exam In hours	Marks		Total
					Internal Assessment	End sem. Exam	
PH 501.2	Genetic Engineering	4	4	3	40	60	100
PH 502.2	Cell and Molecular Biology	4	4	3	40	60	100
PH 503.2 P	Genetic Engineeing	4	2	3	20	30	50
PH 504.2 P	Cell and Molecular Biology	4	2	3	20	30	50
PS 505.2	Industrial Biotechnology	3	3	3	40	60	100
PS 506.2	Clinical Research, IPR and Patents	3	3	3	40	60	100

PS 507.2 P	Industrial Biotechnology	4	2	3	20	30	50
PO 508.2	Quality Assurance and Quality Control in Product Development	3	3	3	40	60	100
Total credits/Marks			**23**				**650**

THIRD SEMESTER

Course Code	Course Title	Teaching hours per week	Credits	Duration of exam In hours	Marks		Total
					Internal Assessment	End sem. Exam	
PH 501.3	Animal Biotechnology	4	4	3	40	60	100
PH 502.3	Plant Biotechnology	4	4	3	40	60	100
PH 503.3P	Animal + Plant Biotechnology	4	2	3	20	30	50
PS 504.3	Enzymology	3	3	3	40	60	100
PS 505.3	Environmental Biotechnology	3	3	3	40	60	100
PS 506.3P	Enzymology +Environmental Biotechnology	4	2	3	20	30	50
PO 507.3	Clinical Drug Development and IPR	3	3	3	40	60	100
Total Credits/Marks			**25**				**600**

FOURTH SEMESTER;

Course Code	Course Title	Teaching hours per week	Credits	Duration of exam In hours	Marks		Total
					Internal Assessment	End sem. Exam	
PH501.4	Project Dissertation/ Internship Report +Viva Voce	34	17	Dissertation and Viva Voce	100	400	500
PS502.4	Immunology	3	3	3	40	60	100
Total credits/Marks			**20**				600

Total 4 semesters credit/marks			**24+2 3+25 +20 =92**				**2500**

Total Marks = 2500 and Total credits = 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: Monosaccharides- 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, chitin, pectin, peptidoglycan. Glycosaminoglycans- structure and functions of Hyaluronate.

Lipids: Classification- structure and properties of – phospholipids, glycolipids, and

sphingolipids. Classification- Fatty acids – short chain, medium chain and long chain; saturated and unsaturated (PUFA & MUFA), essential fatty acids. Structure and function of cholesterol and bile. Triglycerides, structure and properties of lipoproteins- High Density Lipoprotein (HDL), Low density Lipoprotein (LDL), Very Low Density Lipoprotein (VLDL).

UNIT II **(14hrs)**

Structural biology of amino acids, proteins & nucleic acids

Amino acids: Classification based on charge and polarity, based on nutrition - 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: Structure of purines and pyrimidines, ribose and deoxy ribose, nucleoside and nucleotides, Conformation of helix (A, B, Z), Chargaff's rule, properties of DNA - denaturation, renaturation, melting temperature, hyperchromicity, cot curve. RNA: structure and types of RNA (t-RNA, r-RNA, m-RNA & micro-RNAs).

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 and 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 nucleotides 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.

PH 502.1 **MICROBIOLOGY** **Hours:56**

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 Bacteriology and Systematics

History of microbiology, Ultrastructure of bacteria, types, reproduction.

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, Metagenomics.

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: Introduction to Bergey's manual, Phylogenetic classification; Numerical taxonomy; Molecular identification methods – 16S rRNA, Assessing microbial phylogeny (Phylogenetic trees).

UNIT II **(14 hrs)**

Microbial symbiosis and microbiome

***Symbiotic relationships in microorganisms*:** Plant microbe interaction, mutualism, antagonism, parasitism, synergism, commensalism, ammensalism with examples. Pathogenic relationship.

***Plants as microbial habitats*:** Rhizobacteria, mycorrhizae and its types, legume-root nodule symbiosis, factors influencing rhizospheric microorganisms.

***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)**

Introduction to Virology

Viruses and their replication: Classification (General and Baltimore), Viroids, 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).

***Structure and Properties*:** Plant viruses (TMV and Gemini virus); Animal viruses (H1N1, SV40 and Corona); Bacteriophages: T4, lambda phage.

UNIT IV **(14 hrs)**

Economic importance of microorganisms

***Agricultural Microbiology*:** Mass production and field applications of Ectomycorrhizae and Vesicular Arbuscular Mycorrhizae (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 – Poly Hydroxy Butyrate (PHB) and Poly Hydroxy Alkanoate (PHA).

***Pharmaceutical Microbiology*:** Importance of extremophilic microbial diversity in pharmaceuticals and 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.

PH 503.2 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 Alimentarious, USFDA, ISO 22000/ HACCP. Nutraceuticals, prebiotics and probiotics in human diet, Neutragenomics.

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, baking, roasting and frying, pasteurization, microwave heating), dehydration, canning, irradiation, processing using low temperature- refrigeration, freezing, smoking and pickling. Preservation of volatiles, Food additives: definition, types and functions.

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 504.1 P BIOCHEMISTRY AND ANALYTICAL TECHNIQUES

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.
- Demonstrate the handing and applications of various spectrophotometric techniques in biological investigations.
- Apply the principle and procedure of TLC and chromatography as well as elemental analysis.

Course Outcomes:

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

- Investigate and analyse the unknown carbohydrate or amino acid compound present in the given sample qualitatively and quantitatively.
- 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.
- Demonstrate the strengths, limitations and use of various chromatographic techniques including paper, TLC.
- Perform the identification and characterization of various biomolecules using UV Vis spectroscopy, AAS and flame photometry.

List of Practical:

1. Preparation of buffers and solutions.
2. Qualitative analysis of carbohydrates.
3. Qualitative test for amino acids.
4. Estimation of proteins by Lowry's/Biuret/Bradford method.
5. Estimation of Glucose by Anthrone method.
6. Estimation of iodine value of oil/fat.
7. Ascending paper chromatography for separation of amino acids
8. Circular chromatography for separation of carbohydrates
9. TLC for the separation of pigments
10. SDS-PAGE and estimation of molecular weight of Proteins
11. Flame Photometry
12. Elemental Analysis using AAS.

PH 505.1 P MICROBIOLOGY AND FOOD BIOTECHNOLOGY

Course Objectives:

This course enables the students to:

- Understand and appreciate the laboratory safety protocols.
- Become adept with microbiological techniques to isolate, investigate the structure and physiology, identify and preserve the isolated microorganism.
- Acquire skills on various methods of assessing food quality.
- Understand the various tests to detect adulterants in various food samples.

Course Outcome:

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

- 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.
- Evaluate the microbial load in food.
- Analyse the adulterants in various foods and evaluate food quality.

List of Practical:

1. ***Manipulation of microorganisms*:** Pure culture techniques (Streak-plate, pour-plate, and sub-culturing techniques).
2. ***Enumeration of bacteria*:** Standard plate count; Determination of growth by absorbance (Optical density).
3. Staining and observation of microorganisms:

   Staining: Simple staining; Negative staining; Capsular staining; Gram staining; Spore staining.

   Motility determination: Hanging drop slides.

4. **Identification of unknown microorganism:**

   Culture characteristics: 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).

5. ***Environmental factors affecting the growth*:** Temperature; pH
6. Determination of acidity in Curd / Milk –by titration method.
7. Dye reduction test- Methylene Blue & Resazurin test.
8. Turbidity test.
9. Detection of adulterants in Fats and oils/ Milk/other foods.
10. Acid value / Peroxide value / Iodine value of Oil / fat
11. Total acidity in citrus fruits
12. Extractions of Lactose from milk

PS 506.1 MOLECULAR GENETICS Hours: 42

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 (14 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 **(14 hrs)**

Human genetics

Pedigrees-gathering family history, pedigree symbols, construction of pedigrees, Human karyotype construction, Common syndromes due to numerical chromosome changes with egs monosomy**:** Cri- du-chat, trisomy: Down's, Patau, Edwards. Structural alterations - Deletions, microdeletion: Angleman and Prader-Will, 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), in born 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 **(14 hrs)**

Evolutionary genetics

Theories of origin of life-Special creation, Catastrophism, Panspermia, Abiogenesis, Biogenesis (experiments of Francisco 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. l., Levine, M. L., & Losick, R. (2017). Molecular Biology of gene. 7th ed., San Francisco: Pearson Education.

PS 507.1 RESEARCH METHODOLOGY, ETHICS AND SCIENTIFIC COMMUNICATION Hours:42

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:

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 preparation for research, choosing a mentor, lab, maintaining a lab notebook.

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, and Guidelines on Authorship, conflicts of interest, Copy right form and publication misconduct.

Unit II **(14 Hours)**

Research methodology

Selecting and defining a research problem: Criteria for selecting a problem, techniques involved. Research design –Need for Research design, features of a good design, important experimental designs Design of Sample survey-sample design, sampling and non-sampling errors, sample survey Vs Census survey. Types of sampling design- Probability sampling design, Nonprobability sampling design, complex random sampling design.

Data collection – Experiments and surveys, collection of primary data, collection of secondary data, Data preparation

Unit III **(14 Hours)**

Scientific communication

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

Types of reports- research articles/ thesis. Elements of a scientific paper, Styles for citing references, reference managers.

Publishing scientific papers – journal finder, formatting the paper as per instructions of the journal, submission, peer review process, open access. Identifying predatory publishers and journals.

Evaluating scholarly publications: 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; Author level metrics – h-index, g-index, i10 index. Altmetric.

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.

PS 508.1P MOLECULAR GENETICS

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

SEMESTER II

PH 501.2 GENETIC ENGINEERING Hours: 56

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)

Gene Cloning and preparation of libraries:

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 used in gene cloning

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

Agrobacterium based vectors: Ti plasmid - co integrative and binary vectors and their utility.

Viral vectors- Baculovirus based vectors, SV40 vectors, CaMV based vectors, transposon based vectors.

UNIT III **(14 hrs)**

Gene transfer techniques and selection of recombinants

Physical and chemical methods of gene transfer: Biolistics, Microinjection, electroporation, sonoporation, Calcium phosphate co precipitation, Liposome mediated transformation, Poly Ethylene Glycol (PEG), Di Ethyl Amino Ethyl (DEAE) dextran.

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

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, Small Noncoding RNAs (miRNA-seq). Major RNA-Seq platforms- 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.

PH 502.1 CELL AND MOLECULAR BIOLOGY Hours:56

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.
- Apply the concepts of cell and molecular biology in research.

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 signaling. Cell death pathways and their regulation.

Unit II (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. Inhibitors of DNA replication and translation.

Unit III **(14 hours)**

Regulation of Gene expression in Eukaryotes

Regulation at the level of genome-DNA amplification, DNA rearrangement, Chromatin remodeling 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, Translation;al and Post translational control. Genetic basis of differentiation-molecular aspects o;f 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 **(14 hours)**

Molecular basis of cell transformation

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

Genetic basis of Cancer: Cellular oncogenes - Oncogene families: Protein kinases (*Src*), GTP binding proteins (*H-ras, K- ras*), growth factors (*sis*), nuclear proteins (*myc*), hormone receptors (*erbA*) and unclassified. Protooncogenes- activation to oncogenes, and Retroviral oncogenes (*v-src, v-myc*). Tumor suppressor genes-their role in cell cycle control and tumor development (RB, p53).

REFERENCES:

2. 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.
3. Baressi, M. J. F., & Gilbert, S. F., (2019). Developmental Biology, 12th ed., Massachusetts: Sinauer Associates.
4. Brooker, R. J. (2017). Genetic analysis and principle, 6th ed., New York: McGraw Hill Education.
5. Brown, T. A., (2017). Genomes 4, New York: Garland Science, Taylor and Francis group.
6. Cooper, G. M., & Sinauer G.M., (2019). The Cell: A Molecular Approach, International 8th ed., United Kingdom: Oxford University Press.

7. Hardin, J. & Bertoni, G. P. (2018). Becker's World of The Cell, 9th ed., USA: Pearson Education Ltd.
8. Karp, G., Iwasa, J., & Marshall W. (2016). Cell and Molecular Biology: Concepts and Experiments, 8th ed., New York: Wiley & sons.
9. Krebs, J. E., Goldstein, E. S., & Kilpartick, S. T. (2017). Lewin genes- XII, Burlington: Jones and Bartlett Publishers.
10. 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.
11. Tropp, B. E. (2020). Molecular Biology: Genes to Proteins, 5th ed., New York: Jones & Bartlett Learning.

PH 503.2 P GENETIC ENGINEERING

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.
- Apply the knowledge of genetic engineering methods in research.

List of experiments:

1. Extraction of DNA from plant tissue.
2. Purity determination of DNA.
3. Agarose gel electrophoresis of DNA.
4. Isolation of Plasmids-electrophoretic identification of linear, circular and supercoiled DNA.
5. Restriction digestion of lambda DNA using EcoRI.
6. Ligation of restricted DNA of lambda phage using ligase.

7. Calcium chloride mediated transformation of *E.coli* & selection of transformants.
8. Restriction mapping.
9. PCR and determination of the molecular weight of product.
10. Southern blotting technique.
11. Demonstration of Realtime PCR.
12. Western Blotting Technique.

PH 504.2 P CELL AND MOLECULAR BIOLOGY

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.

Course Outcomes:

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

- Assess membrane transport and cell divisions.
- Perform cell measurement and cell counting.
- Isolate cell organelles.
- Perform qualitative and quantitative assays on macromolecules.

List of experiments:

1. Study of plasmolysis in cells of *Rheo* leaves.
2. Use of Micrometry and calibration, measurement of onion epidermal cells and yeast.
3. Cell counting using haemocytometer.
4. Determination of mitotic index in onion root tips.
5. Study of structure of stomata in the epidermal peels of leaves.
6. Melt curve analysis of the given DNA sample.
7. Estimation of DNA by diphenylamine method.
8. Isolation of RNA from coconut endosperm.
9. Agarose gel electrophoresis of RNA.

10. Estimation of RNA by orcinol method.
11. Staining and visualization of mitochondria by Janus green stain.
12. Visualisation of nuclear fraction by Acetocarmine stain.

PS 505.2 INDUSTRIAL BIOTECHNOLOGY Hours: 48

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., Nghiêm, 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. Waites, M. J., Morgan, N. L., Rockey, J. S., & Higton, G. (2009). Industrial microbiology: an introduction. Hong Kong: John Wiley & Sons.
10. Young, M. M. (2019). Comprehensive Biotechnology, 3rd ed., United Kingdom: Pergamon Press.
11. Stanburry, P. F., Whitaker, A., & Hall, S. (2016). Principles of Fermentation Technology, 2nd ed., United Kingdom: Butterworth Heinemann.
12. Waites, M. J., Morgan, N. L., Rockey, J. S., & Higton, G. (2009). Industrial microbiology: an introduction. Hong Kong: John Wiley & Sons.
13. Young, M. M. (2019). Comprehensive Biotechnology, 3rd ed., United Kingdom: Pergamon Press.

PS 506.2 CLINICAL RESEARCH, IPR AND PATENTS HOURS: 48

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 insightinto 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 507.2 P INDUSTRIAL BIOTECHNOLOGY PRACTICALS

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.

OPEN ELECTIVE

PO 508.2 QUALITY ASSURANCE AND QUALITY CONTROL IN PRODUCT DEVELOPMENT HOURS: 42

Course Objectives:

This course enables the students to:

- Understand the best practices, tools and techniques in quality management.
- Acquire knowledge about the principles and applications of the GMP.
- Outline the main GMP requirements related to premises, equipments and personnel from its regulatory and application perspective.
- Comprehend the requirement of Good Documentation Practices and data integrity for medicinal products.

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: **(14 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. 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: **(14 hrs)**

Introduction to GMP

Historical background, principles of GMP, introduction to cGMP, Schedule M.

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: **(14 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, 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.

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.; 8 ed., United States: Wiley-Blackwell.

PH 502.3 PLANT BIOTECHNOLOGY Hours: 56

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, Flavr-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.

PH 503.3P ANIMAL BIOTECHNOLOGY PRACTICAL (Please merge ABT PBT Practical and Course Outcomes)

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).

PLANT BIOTECHNOLOGY PRACTICALS

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:

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

PS 504.3 ENZYMOLOGY Hours: 42

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); enzyme-substrate complex formation and hypothesis. Theories of enzyme catalysis, factors affecting enzyme activity (Temperature, pH, time & substrate concentration).

Co-enzymes - vitamin and nonvitamin coenzymes.

UNIT II
(14 hrs)

Enzymes Kinetics - Derivation of Michaelis Menton equation for single substrate reaction. Lineweaver-Burk, Eddie-Hofstee and Hanes plot.

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

Inhibition kinetics: Reversible - Competitive, non-competitive, uncompetitive, Irreversible - suicide inhibition & its significance. Allosteric inhibition: Aspartate transcarbamoylase - Concerted and sequential models.

UNIT III
(14 hrs)

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

Zymogen activation - Digestive enzymes and blood clotting cascade.

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.

PS 505.3 ENVIRONMENTAL BIOTECHNOLOGY Hours:48

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.

PS 506.3 P **ENZYMOLOGY** **(to be merged with EBT)**

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 Practical:

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

ENVIRONMENTAL BIOTECHNOLOGY PRACTICALS

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.

PO 507.3 CLINICAL DRUG DEVELOPMENT AND IPR Hours: 48

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 GDocP.

- 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 ofClinical 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.

PS 508.1 IMMUNOLOGY Hours: 48

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.

Paper Code **Reg. No.:**

St. Aloysius College
(Autonomous) Mangaluru
Internal Examination- M.Sc. Biotechnology

Paper Name

Time: 1.5 hours **Marks: 50**

Note: Draw schematic sketches wherever necessary

I. Answer any <u>FIVE</u> of the following questions. (3×5= 15)

1.
2.
3.
4.
5.
6.
7.

II. Answer any <u>FOUR</u> of the following questions. (5×4= 20)

8.
9.
10.
11.
12.
13.

III. Answer any <u>ONE</u> of the following. (15×1= 15)

14.
15.
16.

****

Model Question Paper

Paper Code Reg. No:

St Aloysius College (Autonomous), Mangaluru Final Semester I – P.G. Examination – M.Sc. Biotechnology

Time: 3Hours **Max. Marks: 70**

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

I. Write short notes on any <u>FIVE</u> of the following. **(5x3 = 15)**

1.
2.
3.
4.
5.
6.
7.
8.

II. Write explanatory notes on any <u>FIVE</u> of the following. **(5x5 = 25)**

9.
10.
11.
12.
13.
14.
15.
16.

III. Answer any <u>THREE</u> of the following. **(3×10=30)**

17.

18.

19.

20.

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.

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 (independent Practical)

Practical exam **Duration: 3 hours** **Marks: 35**

1. Major experiment (1)	**10 x 1 = 10**
2. Minor experiment (1)	**5 x 1 = 05**
3. Spotters A, B (analytical problem/procedure writing)	**05**
4. Class record	**05**
5. Viva	**10**

End semester (Combined Practical)

Practical exam **Duration: 4 hours** **Marks: 70**

1. Major experiment (2)	**15 x 2 = 30**
2. Minor experiment (2)	**5 x 2 = 10**

3. Spotters A, B, C, D (analytical problem/procedure writing)	**10**
4. Class record	**05**
5. Viva	**15**

Eligibility Criteria for Admission Under St Aloysius (Deemed to be University)

M.Sc. Biotechnology

Candidates must have a Three year B.Sc. degree/ four year integrated BSc degree or Vocational degree in the Sciences (Biotechnology /Biochemistry /Microbiology/Bioscience/ Bioinformatics/Biomedical Science/ Botany/ Zoology/ Agricultural/ Veterinary/Fishery Sciences/Pharmacy/Medical Laboratory Technology) or any branch of Life Sciences from any recognized university with a minimum of 45% marks (40% in case of SC/ST/Category-I candidates) in aggregate excluding languages are eligible* for the programme.

*Students pursuing an International curriculum must note that eligibility is according to Association of Indian Universities stipulations.

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