Syllabus for the 1 year PG Diploma Course in

QUALITY CONTROL AND ASSURANCE IN MICROBIAL TECHNOLOGY

(Semester Based: 400 marks in two semesters)

Department of Microbiology
Vidyasagar University
Midnapore – 721 102
West Bengal

Semester - I

THEORETICAL

Paper 101 ***50 marks***

Gr. A: Microbiology and biotechnology [40 LECTURES]

Methods for study of microorganisms: Microscopy, cultivation, characterization, enumeration. Structure, classification and metabolism of bacteria, fungi, algae and virus. Identification of microbes : morphological, biochemical and molecular. Growth and replication of microbes. Basic idea about viroids, prions. Metabolic biproducts of industrial importance.

Biotechnological aspects – applications of molecular biology and immunology: Gene manipulation, cell culture, monoclonal antibodies, antibody engineering, siRNA, gene therapy, stem cells, skin & tissue engineering.

Basic concepts of various types of biological databases, ISO-OSI Reference Model, Major biological databases for nucleotides and proteins. Primary Sequence & Structure Databases, Searching a biological database, sequence retrieval tool Sequence Alignments, Similarity Searching Tools: BLAST and FASTA, Theory and Algorithms, Statistical Significance, Software for quality assurance and monitoring.

Gr. B: Microbial technology

Bioprocessing: Industrial strains and starter cultures, Selection of media, Fermenters, Fermentation /cell culture, up and down stream processing. Commercially significant fermented products. Production of organic solvents (ethanol, glycerol, acetone / butanol; organic acids: citric, gluconic and acetic acid) Amino acids; Enzymes (e.g. amylases, proteases, lipases, invertase, cellulolytic enzymes). Therapeutic products – vitamins; antibiotics; steroids.

Biopolymers, bioplastics. Bioremediation. Sewage treatment: solid waste and waste water.

Safety, Health and Environment (SHE).

Puper 102 ***50 marks***

Gr. A: Introduction to Laboratory Safety

Safe laboratory practices, regulatory agencies, handling & storage of chemicals, reagents, microbial specimens and its preservation, types of contamination and control, disposal of contaminated wastes, safety of personnel, protective equipment, emergency response. Biological hazard.

Gr. B: Quality assurance in pharmaceutical industry

Basic idea about pharmaceutical products (bulk drugs/ dosage forms, vaccines, diagnostics) and quality requirements. Quality Assurance (QA) and validation in Pharmaceutical Industry. Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Quality Control (QC), Regulations, Practices & Procedures, Statistical validation. Quality Management System.

PRACTICAL

Paper 103 ***50 marks***

Microbial techniques

1. Qualitative and quantitative enumeration of microorganisms [bacteria (aerobes and anaerobes), molds and yeasts, and algae] from soil, water and air.
2. Study of bacterial and yeast growth, kinetics, effect of inhibitors and stimulators on growth.
3. Extraction and estimation of protein, carbohydrate, DNA and RNA of a bacterial cell.
4. Purification of enzyme.
5. Determination of MW of protein by SDS- PAGE.
6. Western blotting analysis of protein.
7. Agarose gel electrophoresis for DNA.
8. Amplification of DNA / RNA by PCR.
9. Restriction analysis of bacterial DNA.

Paper 104 ***50 marks***

Group A: Bioinformatics

1. Pair wise alignment, multiple alignment and data-base searching.
2. Molecular Phylogenetics: Tree construction methods (Distance and character based methods). Suffix tree construction.
3. DNA and protein sequence analysis : online and local tools like EMBOSS package and expasy online prediction tools
4. Programming basics, tool development and software quality assurance and monitoring.

Group B : Quality control in Microbiology Laboratory

1. Document preparation for QA/QC norms of different sectors.
2. Quality control in Microbiology laboratory, assessment of aseptic condition, evaluation of possible channels of contamination, QA/QC norms for handling pathological samples.

Semester - II

THEORETICAL

Paper 201 ***50 marks***

Gr. A : Genetic engineering

Processing of recombinant protein: Purification, refolding,characterization and stabilization.

Immunodiagnostics: Immunological reactions including ELISA, RIA, Immunofluorescence.

Biopharmaceuticals: Production of therapeutic proteins, live and attenuated vaccine.

Transgenic and gene knockout technologies, Genetically modified organism (GMO),

Cell and tissue culture (plant and animal).

Biosafety regulations, Good Large-scale Practice (GLSP), quality control and quality assurance for products / processes involving GMO. Intellectual Property Rights (IPR).

Gr. B : Food: Processing and Production

Principles of Food preservation: Food and microorganisms. Food processing and preservation.

Production of Brewer's yeast and Baker's yeast. Single cell proteins.

Probiotics and prebiotics.

Fermented food: Production and application of dairy products, vegetables and beverages.

Alcoholic fermented beverages.

Production of biofertilizers and biopesticides.

Paper 202 ***50 marks***

Gr. A : Food safety

Food additives and their effects on microorganisms and humans. Natural toxicants in food products, mycotoxins, Food contaminants and diseases. Regulations: Food Safety and Standards Authority of India (FSSAI). Silent features of Food Safety and Standards Act (FSSA), 2006.

Gr. B : Food Quality Assurance and Validation

Microbiological criteria of food, food products, beverages and water. Microbial quality assurance, monitoring of factory hygiene and sanitation, microbiological quality of ingredients, processing and finished products with regard to specified standards. Microbiological quality of oil and fats, rancidity. Quality assurance and validation principles and their applications in industries related to food and beverage. FDA rationale, Good Practices and documentation requirements. Hazard Analysis Critical Care Points (HACCP).

PRACTICAL

Paper 203 ***50 marks***

Gr. A : Microbial processing

1. Production of alcohol by fermentation from molasses.
2. Preparation of baker's yeast using molasses.
3. Microbial production of amylase (Solid, Liquid & Submerged fermentation).
4. Immobilization of amylase/invertase and study of its catalytic activity.
5. Production of curd with respect to microbial load and organic acid formation.
6. Estimation of microbial endotoxins.
7. Tissue culture

Gr. B : Quality monitoring:

Assessment of quality of various grains, seeds, food and food products, microbial media, water samples, Assessment of quality of pharmaceutical samples

Paper 204 ***50 marks***

Survey and short term-training in biotech, food, beverage and pharmaceutical industry and report preparation on the topics (Quality control, Quality assurance, Validation, Regulatory affairs)