

BACE

Biotechnology
Aptitude and
Competency
Exam

AY 25-26

All

DETAIL OF EXAM CATEGORIES

Knowledge Categories

Technical Skills & Applications

Technical Skills & Applications covers the foundational techniques used in biotechnology workplace settings. It includes understanding and applying methods such as aseptic technique, cell culture, DNA isolation, and various assays. The focus is on both the theoretical principles and the practical application of these techniques, including the use of advanced equipment and procedures such as polymerase chain reaction (PCR), gel electrophoresis, and chromatography.

- Discuss current techniques used in biotechnology and their applications
- Describe the proper use of microscopes
- Discuss cell staining, and distinguish between gram-positive/negative cells
- Describe the process of culturing microorganisms and tissues using aseptic technique
- Discuss the differences between sterilization, decontamination, and disinfection
- Understand the principle by which a pH meter works
- Explain the principles of spectrophotometry, including Fourier-transform infrared (FT/IR) spectrophotometry
- Understand the basic principle of the Beer-Lambert law
- Discuss methods of chromosomal and plasmid DNA isolation, purification, and quantification
- Discuss gel electrophoresis techniques, including agarose and polyacrylamide gel electrophoresis (PAGE)
- Understand how restriction enzymes are used
- Describe recombinant DNA and cloning techniques
- Describe the mechanism of PCR, including the theory and practical use of conventional and real-time PCR (qPCR) thermal cyclers
- Discuss protein expression in model organisms
- Discuss methods of molecule/protein isolation, purification, and quantification
- Understand the principles of enzyme-linked immunosorbent assay (ELISA) and other immunoassays
- Understand molecular diagnostic techniques and their applications
- Discuss assay development and validation
- Understand the principles and applications of flow cytometry and cell sorting
- Discuss the principles of centrifugation and its applications
- Understand the basics of chromatography techniques

- Discuss transformation and transfection of model organisms
- Understand applications of lab automation and robotics in biotechnology
- Demonstrate an understanding of how calibration and validation are critical to producing reliable, consistent results
- Discuss the principles and applications of laminar flow in a cleanroom or manufacturing environment

Safety & Workplace Culture

Safety and Workplace Culture emphasizes the importance of safety, ethics, and proper behavior in the biotechnology workplace. It includes understanding and following safety protocols, using personal protective equipment (PPE), handling hazardous materials, and responding to emergencies. It also covers the ethical considerations in biotechnology, workplace behaviors, and compliance with regulations enforced by agencies such as the Occupational Safety and Health Administration (OSHA).

- Discuss ethics and bioethics in the workplace and society
- Describe appropriate workplace behaviors
- Identify proper workplace safety behaviors
- Identify safety symbols
- Identify and explain proper use of safety equipment
- Identify and properly use PPE
- Exercise proper safety protocols
- Describe proper handling of biological and hazardous waste
- Explain the importance of posting and complying with signage
- Describe procedures for safe handling and storage of chemicals
- Derive information from safety data sheets (SDS)
- Discuss key OSHA regulations applicable to biotechnology workplaces
- Describe proper lockout/tagout procedures for machinery and equipment
- Describe emergency response procedures for fires, chemical spills, or other incidents
- Discuss the process for reporting safety concerns and hazards, including near misses
- Discuss the importance of proactive safety communication
- Understand the importance of comprehensive training and safety training in biotechnology workplaces
- Properly label items, including solutions, buffers, Petri plates, samples, and products

Biochemistry & Molecular Biology

Biochemistry & Molecular Biology focuses on the molecular and biochemical principles that underpin biotechnology. It includes understanding DNA structure and function, gene expression, protein synthesis, enzyme activity, and cell biology. It also covers processes and techniques related to molecular biology and protein expression, such as monoclonal antibody production, immunotherapy, and the role of mRNA in therapeutics.

- Understand the chemistry of molecules and macromolecules

- Describe DNA structure and function
- Describe transcription
- Describe translation and gene expression
- Describe protein structure and function
- Explain how enzymes function and affect reaction rates
- Understand cell settling and centrifugation techniques
- Discuss proper techniques for mixing solutions and preparing reagents
- Understand the general physiology of cells
- Explain the interaction between cells, and between cells and their environment
- Understand the genetics of model organisms
- Discuss monoclonal antibody (mAb) production and applications
- Understand the role of mRNA in cellular function and therapeutics
- Discuss immunotherapy types and applications, such as chimeric antigen receptor T-cell (CAR-T) and mAb

Regulation & Quality

Regulation & Quality involves understanding the regulatory environment and quality practices associated with the development, manufacture, and testing of biotechnology-based products and processes. It covers the roles of current Good Laboratory Practices (CGLP), current Good Manufacturing Practices (CGMP), Good Documentation Practices (GDocP), and regulatory agencies such as the Food and Drug Administration (FDA). It also includes knowledge of the processes involved in product development, regulatory approval, departmental roles, and maintaining data integrity and security.

- Discuss regulatory agencies governing the manufacture and distribution of biotechnology-derived products
- Outline the role of various departments in a company, including Research and Development (R&D), Quality Assurance (QA), Quality Control (QC), and Manufacturing
- Understand the purpose of CGLP in non-clinical studies
- Understand the purpose of CGMP
- Follow practices associated with regulatory compliance
- Discuss key components of GDocP, including contemporaneous documentation, controlled documents, and approvals
- Identify the proper use and essential elements of CGMP documents, such as Standard Operating Procedures (SOP), batch records, logs, and deviation reports
- Explain the objectives of research and development with the goal of launching an FDA regulated product.
- Explain the FDA approval process for regulated products
- Outline the manufacturing process in bioprocessing and production facilities
- Discuss Upstream (USP) and Downstream Processing (DSP), including the key steps and equipment involved in each process
- Describe Environmental Monitoring (EM) in a controlled space
- Understand the importance of audits and Corrective and Preventive Actions (CAPA) to ensure compliance and continuous improvement

- Discuss Attributable, Legible, Contemporaneous, Original, and Accurate (ALCOA) principles and FDA guidelines on data integrity and compliance
- Discuss strategies for maintaining security of sensitive data and intellectual property
- Describe the significance of Health Insurance Portability and Accountability Act (HIPAA) compliance and the protection of personal health information

Practical Categories

Biotechnology Skills

Biotechnology Skills centers on technical skills essential for quality work. It includes accurately measuring liquids and solids, preparing solutions, performing serial dilutions, and using standard equipment such as centrifuges, spectrophotometers, and biosafety cabinets. The focus is on mastering these practical skills to ensure precise and reliable outcomes.

- Accurately measure liquids with micro and macro scale equipment
- Accurately measure mass using electronic balances
- Properly prepare solutions and buffers
- Properly measure and adjust the pH of a solution
- Properly perform a serial dilution
- Identify and properly handle reagents
- Demonstrate proper aseptic/sterile technique
- Demonstrate proper culturing of microorganisms
- Describe the proper use of a centrifuge
- Describe the proper use of a spectrophotometer
- Describe the proper use and maintenance of biological safety cabinets (BSC)
- Demonstrate proper use of electrophoresis equipment
- Discuss the role and impact of automation in the biotechnology industry
- Use 24-hour time correctly

Applied Mathematics

Applied Mathematics covers the mathematical skills needed to perform common bioscience workplace calculations and data analysis. It includes using scientific notation, significant digits, metric conversions, making dilutions, calculating weight and volume measurements for buffer and media prep, graphing data, and performing statistical analyses. These skills are crucial for designing experiments, preparing reagents and solutions, and interpreting results.

- Use scientific notation correctly
- Use significant digits correctly
- Understand and use mathematical symbols
- Understand and use fractions
- Use metric measurements and perform metric unit conversions
- Generate a graph using collected data
 - Properly plot data

- Interpret data
- Generate a standard curve
- Perform calculations for serial dilutions
- Perform calculations using dilution factors
 - Solve Dilution Factor calculations
 - Solve Molarity solution calculations
 - Solve Volume/Volume (V/V) solution calculations
 - Solve Weight/Volume (W/V) solution calculations
- Describe the relationship between pH measurements and the logarithmic scale
- Apply basic statistical techniques such as mean, median, mode, and standard deviation to analyze data

Standard Equipment

Standard Equipment focuses on the proper identification, use, and maintenance of standard equipment. It includes understanding the safe operation of micro and macro pipettes, balances, pH meters, centrifuges, and other essential tools. Mastery ensures an aptitude for the accurate and safe handling of equipment, and critical parameters such as calibration, maintenance, and validation.

- Identify common glassware and equipment
- Demonstrate proper and safe use of

<ul style="list-style-type: none"> ○ micropipettes & serological pipets ○ electronic balances ○ pH meters ○ stirrers/shakers ○ vortexers ○ water baths ○ autoclaves ○ BSC 	<ul style="list-style-type: none"> ○ fume hoods ○ centrifuges ○ spectrophotometers ○ microscopes ○ electrophoresis equipment ○ incubators ○ heat/cool blocks ○ chromatography equipment
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Experimental Design & Data Analysis

Experimental Design & Data Analysis involves understanding how to design experiments, analyze data, and communicate findings effectively. It covers the use of controls, maintaining a laboratory notebook, applying statistical methods, and adhering to the principles of Responsible Conduct of Research (RCR). The focus is on ensuring that experiments are well-designed, data is accurately interpreted, and results are clearly communicated.

- Read, interpret, and draw conclusions from technical material, test records, and specification sheets
- Discuss good experimental design, including the proper use of controls
- Explain how to maintain a laboratory notebook
- Analyze and interpret data, including the use of statistical analysis
- Understand and apply the principles of RCR
- Demonstrate proper implementation of data integrity principles

- Effectively communicate scientific findings
- Understand applications of Principal Component Analysis (PCA)
- Identify and analyze sources of error in assay results
- Discuss the role of sample size and replication for study design

Definitions

Agarose Gel Electrophoresis: A method used to separate DNA or RNA molecules based on their size by applying an electric field to an agarose gel matrix. The agarose gel acts as a sieve, allowing smaller molecules to move faster through the gel while larger molecules move more slowly, enabling the separation and analysis of nucleic acids.

Aseptic Technique: A set of practices used to prevent contamination by pathogens or unwanted microorganisms during procedures, crucial for maintaining sterile conditions in cell culture and other sensitive processes.

Attributable, Legible, Contemporaneous, Original, and Accurate (ALCOA): Principles that ensure data integrity in regulated environments, ensuring that data is reliable, accurate, and trustworthy.

Autoclave: A device used to sterilize equipment and materials using high-pressure steam, commonly used in laboratory, industrial, and medical settings to ensure that tools and materials are free of microbial contamination.

Automation: The use of technology to automate biotechnology processes, increasing efficiency and reducing human error, commonly employed in high-throughput screening and sample processing.

Batch Record: A controlled document that contains instructions for manufacturing a regulated product. It also captures contemporaneous data relevant to the manufacture of that product.

Beer-Lambert law (also written Beer's Law): A principle that describes the linear relationship between the concentration of a solute in a solution and the absorbance of light at a particular wavelength, used in quantitative spectrophotometry.

Buffer: A solution that resists changes in pH when small amounts of acid or base are added, commonly used in biological experiments to maintain a stable pH environment.

Biosafety Cabinet (BSC): Enclosed, ventilated workspace designed to protect the user, the product, and the environment from exposure to biohazards and contamination.

Calibration: The process of adjusting and standardizing the measurements of an instrument or device to ensure accuracy and reliability, which is essential for maintaining data integrity.

Cell Culture: The process of growing cells in a controlled, artificial environment, typically using a nutrient-rich culture medium, for research, production of biologics, or other biotechnological applications.

Cell Sorting: A method of separating cells based on specific characteristics, often using flow cytometry to isolate particular cell types for further study or therapeutic use.

Cell Staining: The process of applying dyes to cells or tissues to enhance contrast under a microscope, enabling the visualization of cellular components, often used in identifying cell structures or distinguishing between cell types.

Centrifuge: A machine that spins samples at high speeds to separate components based on their density, commonly used to isolate cells, organelles, or macromolecules in biological research.

Chromatography: A technique for separating and analyzing the components of a mixture based on their different interactions with a stationary phase and a mobile phase, commonly used in protein purification, drug testing, and biochemical analysis.

Cloning Techniques: Methods used to create copies of DNA fragments, cells, or organisms, often used in research, therapeutic applications, and genetic engineering.

Corrective and Preventive Actions (CAPA): A systematic approach used in manufacturing and quality management to identify, investigate, and correct the root causes of problems to prevent their recurrence. Corrective actions address immediate issues, while preventive actions focus on eliminating potential future problems.

Current Good Manufacturing Practices (CGMP): Regulations enforced by the FDA to ensure that products are produced in a consistent and controlled manner according to quality standards, covering all aspects of manufacturing.

DNA Isolation: The process of extracting DNA from cells or tissues, allowing it to be used for various downstream applications such as PCR, sequencing, or cloning.

Downstream Processing (DSP): The phase that follows upstream processing in bioprocessing, involving the purification and recovery of the product from the complex mixture produced during upstream processing. It includes techniques such as filtration, chromatography, and crystallization to isolate and purify the final product.

Electrophoresis Equipment: Instruments used to perform gel electrophoresis, a technique for separating DNA, RNA, or proteins based on their size and charge.

Enzyme-linked Immunosorbent Assay (ELISA): A plate-based assay technique used to detect and quantify specific proteins, antibodies, or hormones, widely used in diagnostics and research.

Environmental Monitoring (EM): Involves the systematic collection of data to detect contaminants in a controlled environment, such as a cleanroom or manufacturing facility. It ensures that the environment meets specified cleanliness and safety standards, crucial for maintaining product quality in industries like biotechnology and pharmaceuticals.

Flow Cytometry: A technology used to analyze the physical and chemical characteristics of cells or particles as they pass through a laser, allowing for the measurement of various cellular properties, including size, complexity, and fluorescence.

Food and Drug Administration (FDA): A regulatory agency of the United States Department of Health and Human Services responsible for protecting public health by ensuring the safety, efficacy, and security of drugs, biological products, medical devices, food, and cosmetics. In the biotech industry, the FDA regulates the development, testing, manufacturing, and approval of biotechnological products, including pharmaceuticals, vaccines, and diagnostic tools.

Fourier-transform Infrared (FT/IR) Spectrophotometry: A type of infrared spectroscopy that collects spectral data over a wide range of wavelengths simultaneously, used to identify chemical bonds and molecular structures.

Gel Electrophoresis: A method used to separate mixtures of DNA, RNA, or proteins based on their size and charge by applying an electric field to a gel matrix, causing molecules to migrate through the gel.

Good Documentation Practices (GDocP): Guidelines for accurately recording and maintaining documents, ensuring they are complete, consistent, and easily retrievable, which is critical in regulated environments.

Good Laboratory Practices (GLP): A set of principles intended to ensure the quality and integrity of non-clinical laboratory studies, regulated by agencies like the FDA.

Gram Staining: A differential staining technique that distinguishes between Gram-positive and Gram-negative bacteria based on the properties of their cell walls, used for bacterial classification and diagnosis.

Health Insurance Portability and Accountability Act (HIPAA): U.S. legislation that provides data privacy and security provisions to safeguard medical information, ensuring that personal health information is protected.

Immunoassay: A biochemical test that measures the presence or concentration of a substance in a solution using the reaction of an antibody or antibodies to its antigen.

Immunotherapy: A type of treatment that uses the immune system to fight diseases such as cancer, often involving the use of monoclonal antibodies, CAR-T cells, or other immune-modulating therapies.

Incubator: A device used to maintain a controlled environment, typically with regulated temperature and humidity, for the growth and development of microorganisms or cell cultures.

Laminar Flow: A smooth, uniform flow of air in one direction, typically used in cleanrooms or biosafety cabinets to prevent contamination during sensitive procedures.

Manufacturing: The department within a drug manufacturing company responsible for producing the product. This department is also sometimes referred to as "Production."

Micropipette: Precision instrument used to measure and transfer small volumes of liquid, essential for accurate experimental work.

Microscopy: The use of microscopes to view and analyze structures that are too small to be seen with the naked eye, such as cells, tissues, or microorganisms.

Monoclonal Antibody (mAb): Antibodies that are identical and produced by a single clone of cells, used in various therapeutic and diagnostic applications due to their specificity for a particular antigen.

Occupational Safety and Health Administration (OSHA): A regulatory agency of the United States Department of Labor that is responsible for ensuring safe and healthy working conditions for employees by setting and enforcing workplace safety standards. OSHA provides training, outreach, education, and assistance to employers and workers, and it enforces compliance through inspections and penalties.

Personal Protective Equipment (PPE): Equipment worn to minimize exposure to hazards that can cause serious workplace injuries or illnesses, including items such as gloves, masks, goggles, and lab coats.

Polyacrylamide Gel Electrophoresis (PAGE): A technique used to separate proteins or smaller DNA/RNA fragments based on their size and charge by applying an electric field to a polyacrylamide gel. The polyacrylamide gel provides a high-resolution medium for the separation of molecules, making it particularly useful for protein analysis and the study of small nucleic acid fragments.

Polymerase Chain Reaction (PCR): A technique used to amplify small segments of DNA by generating thousands to millions of copies of a particular DNA sequence, often used in molecular biology for various applications such as cloning, gene expression analysis, and genotyping.

Principal Component Analysis (PCA): A statistical method used to reduce the dimensionality of data while preserving as much variance as possible, often used in data analysis to simplify complex datasets.

Quality Assurance (QA): The department within a drug manufacturing company responsible for ensuring compliance with CGMP. QA reviews and approves documentation, oversees personnel training, and has the ultimate authority to release or reject a product.

Quality Control (QC): The department within a drug manufacturing company responsible for performing all required testing to ensure that the final product meets its specifications.

Reagent: A substance or compound that is added to a system to cause a chemical reaction or test for the presence of another substance, widely used in experiments.

Real-Time PCR (also known as quantitative PCR, qPCR): A laboratory technique used to simultaneously amplify and quantify a targeted DNA molecule. It allows the detection of the amount of a specific DNA sequence in real-time as the amplification process proceeds, typically using fluorescent markers that emit signals in proportion to the amount of DNA.

Recombinant DNA: DNA molecules that are artificially created by combining DNA from different organisms, used in genetic engineering to express new genes in host cells.

Research and Development (R&D): Refers to the process or department through which companies and organizations develop new products, technologies, or processes, and improve existing ones. In the biotech industry, R&D involves scientific research to discover new biological insights, develop innovative therapies, improve manufacturing processes, and create new biotechnological products such as drugs, vaccines, and diagnostic tools.

Responsible Conduct of Research (RCR): The ethical and professional standards that guide researchers in the planning, conduct, and reporting of research. It encompasses principles such as honesty, accuracy, efficiency, and objectivity in scientific work. In the biotech industry, RCR is critical for ensuring the integrity of research processes, including the proper handling of data, ethical treatment of human and animal subjects, and the transparent reporting of research findings.

Restriction Enzyme: A protein that cuts DNA at a specific sequence, used in molecular cloning, genetic engineering, and various molecular biology applications to manipulate DNA.

Safety Data Sheet (SDS): A document that provides information on the properties of a chemical substance, including handling, storage, and emergency measures, required by OSHA for hazardous chemicals.

Serial Dilution: A stepwise dilution of a substance in solution, used to reduce the concentration of cells, bacteria, or viruses, making it easier to measure or quantify them.

Spectrophotometer: An instrument used to measure the intensity of light absorbed by a sample, used in quantifying nucleic acids, proteins, and other molecules.

Standard Curve: A graph used in quantitative analysis that plots known concentrations of a substance against their corresponding measurement signals, allowing for the determination of unknown concentrations in samples.

Standard Operating Procedure (SOP): Detailed, written instructions to achieve uniformity in performing specific functions, essential for ensuring consistency and compliance in laboratory and manufacturing processes.

Sterilization: The process of eliminating all forms of life, including microorganisms, from an object or environment, usually achieved through heat, chemicals, or radiation.

Test Record: A controlled document that provides instructions for testing a regulated product after its production. It also captures contemporaneous data relevant to the identity, safety, efficacy, potency, purity, and quality of the product.

Transfection: The process of introducing nucleic acids (DNA or RNA) into eukaryotic cells, often used in research to study gene function and protein expression.

Transformation: The genetic alteration of a cell resulting from the direct uptake and incorporation of exogenous genetic material, typically used in bacteria to introduce new genes.

Upstream Processing (USP): Refers to the initial phase of bioprocessing where biological materials (such as cells or microbes) are prepared, grown, and optimized to produce a desired product, such as proteins or other biomolecules. This phase often includes cell culture, fermentation, and optimization of growth conditions.

Validation: The process of proving that a method, process, or piece of equipment consistently produces results that meet predetermined criteria, essential for ensuring quality and reliability in biotechnology.

Vortexer: A device used to mix small vials of liquid quickly and thoroughly by creating a vortex, commonly used in sample preparation.

Water Bath: Equipment that uses heated water to incubate samples at a constant temperature over a period of time, often used in biological and chemical experiments.