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A Comprehensive Review on Microbiological Testing in the Pharmaceutical, Nutraceutical and Cosmetics Industries: Safety Assurance and Regulatory Standards

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A B S T R A C T

Microbiological testing is a critical component of quality assurance in the pharmaceutical, nutraceutical, and cosmetic industries, where microbial contamination can compromise product safety and pose significant health risks, particularly to immunocompromised or vulnerable populations. This review systematically examines key microbiological assays, including sterility testing, bacterial endotoxin assessment, microbial limit testing, and preservative efficacy evaluation. This review further analyzes the regulatory landscape governing these practices, with particular emphasis on standards established by the United States Pharmacopeia (USP), U.S. Food and Drug Administration (FDA), and internationally harmonized guidelines. The integration of robust microbiological quality control measures and adherence to regulatory standards are underscored as essential to ensuring product integrity and protecting public health.

Introduction

Ensuring the microbiological safety of pharmaceutical, nutraceutical, and cosmetic products is a fundamental aspect of public health protection, product quality assurance, and regulatory compliance. These industries develop and distribute a wide range of products that are either ingested, applied topically, or administered parenterally. Given their direct interaction with the human body, the risk of contamination by pathogenic or opportunistic microorganisms represents a serious safety concern. Microbial contamination not only diminishes product efficacy and shelf life but also poses significant health risks particularly to immunocompromised individuals, neonates, the elderly, and patients with chronic illnesses.

Microorganisms such as *Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans*, and bacterial endotoxins can be introduced at various stages of product development, including raw material handling, manufacturing, packaging, and storage. Inadequate microbial control may result in product recalls, regulatory action, or adverse patient outcomes. Consequently, microbiological testing serves as a critical barrier in the quality control process to detect, quantify, and eliminate harmful contaminants.

Routine microbiological assessments include sterility testing for sterile products, bacterial endotoxin testing (BET) to detect pyrogens, microbial limit testing (MLT) for non-sterile products, and preservative efficacy testing (PET) to evaluate the antimicrobial effectiveness of added preservatives. Each test is selected based on the product's intended use, formulation, route of administration, and risk profile. These testing methodologies are complemented by environmental monitoring and in-process controls that help maintain aseptic conditions and prevent microbial ingress during manufacturing (Cristianne *et al.,* 2022). Globally recognized regulatory authorities such as the United States Pharmacopeia (USP), U.S. Food and Drug Administration (FDA), European Pharmacopoeia (Ph. Eur.), Japanese Pharmacopoeia (JP), and the International Council for Harmonisation (ICH) have established comprehensive guidelines that standardize microbiological testing procedures. These regulations specify acceptable microbial limits, validate testing methodologies, and provide frameworks for risk assessment and quality assurance. In an era of increasing globalization and regulatory scrutiny, compliance with these standards is critical not only to meet legal requirements but also to enhance product reliability and consumer trust in highly regulated markets (Palem *et al.,* 2012).

Given the growing complexity of formulations, innovations in biologics and biotechnology, and the expansion of global supply chains, microbiological quality control has become more sophisticated and essential than ever. This review provides an in-depth examination of the key microbiological tests employed across the pharmaceutical, nutraceutical, and cosmetic sectors. It also explores the regulatory landscapes that shape these practices, drawing comparisons across international guidelines and identifying best practices. By integrating scientific methodology with regulatory expectations, this review emphasizes the indispensable role of microbiological testing in ensuring product safety, maintaining compliance, and protecting public health.

Microbiological Testing in the Pharmaceutical Industry

The pharmaceutical industry is subject to some of the most stringent quality and safety requirements in the life sciences sector, owing to the direct impact of its products on human health. Pharmaceuticals, including small-molecule drugs, biologics, and medical devices, must meet strict microbiological standards to ensure they are free from harmful microbial contamination (Palem *et al.,* 2011; and China Reddy *et al.,* 2015). The presence of microorganisms, endotoxins, or resistant pathogens in these products can result in adverse effects ranging from reduced therapeutic efficacy to life-threatening infections—especially in vulnerable populations such as immunocompromised patients, neonates, and the elderly. Microbiological testing serves as a critical safeguard throughout the pharmaceutical manufacturing lifecycle (Fatimah *et al.,* 2024), from raw material sourcing to final product release. It provides robust mechanisms for detecting, quantifying, and controlling microbial contaminants, thereby ensuring compliance with regulatory standards such as those outlined in the United States Pharmacopeia (USP <61>, <62>, <71>, <85>, <1116>), European Pharmacopoeia, and FDA's Current Good Manufacturing Practices (cGMP) (Mahboob *et al.,* 2016). Below are the principal microbiological testing approaches used in pharmaceutical quality control and detailed methodology (Gurajala, 2024), tested for, sample type, regulatory acceptance limit and Compendial References are tabulated in table 1.

Sterility Testing: This is essential for parenteral drugs, ophthalmic solutions, and other sterile products. It confirms the complete absence of viable microorganisms under controlled laboratory conditions. This test is critical for injectable and implantable products, where even minimal contamination can lead to sepsis or systemic infections.

Bacterial Endotoxin Testing (BET): Also known as the Limulus Amebocyte Lysate (LAL) test, BET detects the presence of pyrogenic endotoxins produced by Gram-negative bacteria. These toxins can induce fever, inflammation, and in severe cases, septic shock. BET is mandatory for injectable drugs and medical devices that come into contact with blood or cerebrospinal fluid.

Microbial Limit Testing (MLT): Applied to non-sterile products, MLT ensures that microbial counts remain within pharmacopeial safety thresholds (Mukati *et al.,* 2022). This includes total aerobic microbial count (TAMC), total combined yeast and mold count (TYMC), and absence of specified objectionable organisms like *E. coli*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus*.

Antimicrobial Effectiveness Testing (AET): Also referred to as preservative efficacy testing, AET evaluates a product's ability to inhibit microbial growth over time. This is particularly important for multi-dose

products where repeated exposure during use can introduce contaminants.

Pathogen Identification and Characterization: Advanced molecular techniques such as polymerase chain reaction (PCR), DNA sequencing, and matrix-assisted laser desorption/ionization-time of flight (MALDI-TOF) mass spectrometry are used to detect and identify pathogenic microorganisms in raw materials, intermediates, and final products. This allows for targeted corrective actions and contamination source tracing.

Preservative Efficacy Testing: Distinct from AET in scope, this test specifically assesses the long-term effectiveness of antimicrobial preservatives in preventing microbial proliferation during a product's shelf life.

Environmental Monitoring (EM): A cornerstone of aseptic manufacturing, EM involves routine sampling of air, surfaces, personnel, and equipment in cleanrooms and controlled environments. It ensures the production space remains within acceptable microbial contamination levels and adheres to ISO Class cleanroom standards.

Raw Material Microbial Testing: Raw materials, especially those of natural or biological origin, can be significant sources of microbial contamination. Pre-qualification and routine microbial testing of excipients, active pharmaceutical ingredients (APIs), and packaging materials are crucial to preventing downstream contamination.

Antibiotic Resistance Profiling: With the rise in multidrug-resistant organisms, testing for antibiotic resistance patterns in isolated microbes is increasingly important. It informs product safety risk assessments and supports the development of effective antimicrobial therapies.

Through the integration of these microbiological tests, the pharmaceutical industry upholds the highest standards of product integrity and patient safety. Regulatory agencies across the globe mandate the implementation of these quality control measures to minimize risk, maintain batch consistency, and ensure that all pharmaceutical products meet established microbiological safety criteria.

Microbiological Testing in the Nutraceutical Industry

The global nutraceutical industry which encompasses dietary supplements, functional foods, herbal extracts, and fortified beverages has experienced significant growth driven by increasing consumer demand for health-promoting and preventive wellness products (Baba-Moussa *et al.,* 2013).

However, despite their natural or food-based origin, nutraceuticals are not immune to microbial contamination. Many of these products contain botanical materials, probiotics, or other biologically derived components that can serve as growth substrates for bacteria, yeasts, and molds. Therefore, robust microbiological quality control is essential to ensure product safety, regulatory compliance, and consumer trust (Mane *et al.,* 2023).

Unlike pharmaceuticals, nutraceuticals are often regulated under food or dietary supplement frameworks, which may vary by region (e.g., FDA's Dietary Supplement Health and Education Act [DSHEA] in the U.S., or EFSA guidelines in the EU) (Shikha *et al.,* 2017). However, across jurisdictions, microbial testing remains a critical component of good manufacturing practices (GMP) and hazard analysis and critical control point (HACCP) systems in nutraceutical production. Key microbiological tests commonly implemented in the nutraceutical industry, detailed methodology, tested for, sample type, regulatory acceptance limit and Compendial References are tabulated in table 2.

Microbial Contamination Control: This encompasses total aerobic microbial count (TAMC) and total yeast and mold count (TYMC) to assess the overall microbial load. It helps to determine whether microbial levels are within acceptable safety thresholds. Excessive microbial counts can lead to spoilage, reduced efficacy, and potential health risks, especially in immunocompromised individuals.

Pathogen Detection: Specific testing for pathogenic microorganisms such as *Salmonella spp.*, *Escherichia coli*, *Listeria monocytogenes*, and *Staphylococcus aureus* is mandatory for many nutraceuticals, particularly those derived from plant or dairy sources. Advanced techniques such as PCR (polymerase chain reaction) and ELISA (enzyme-linked immunosorbent assay) offer rapid and sensitive detection of these pathogens.

Yeast and Mold Testing: High moisture content, organic plant matter, and improper storage conditions make nutraceutical products particularly susceptible to fungal contamination. Yeast and mold testing are critical for powdered supplements, herbal products, and probiotics to prevent mycotoxin production and spoilage.

Bacterial Endotoxin Testing: While not universally required, endotoxin testing using the Limulus Amebocyte

Lysate (LAL) assay is increasingly applied to liquid nutraceuticals and parenteral nutrition products, especially those intended for vulnerable populations (Veronika *et al.,* 2016).

Antimicrobial Effectiveness Testing (AET): For multi-use or reconstitutable products, AET evaluates the preservative system's ability to inhibit microbial growth after repeated exposure. This is essential for products stored over time or those requiring refrigeration.

Raw Material Testing: Herbal extracts, plant powders, and other raw materials can be primary sources of contamination. Routine microbiological testing of incoming materials ensures contaminants are not introduced during manufacturing.

Probiotic Testing: For products containing live microorganisms, such as probiotic capsules or yogurts**,** testing is required to confirm strain identity, viability**,** and colony-forming unit (CFU) counts throughout the product's shelf life. Viability is crucial to the claimed health benefits.

Preservative Testing: This involves verifying the efficacy of preservatives or natural antimicrobials in preventing spoilage and extending shelf life. It is particularly relevant for liquid supplements and beverages (Zahraa Amer *et al.,* 2025).

Microbiological Testing in the Cosmetic Industry

Microbiological testing plays a pivotal role in the cosmetics industry, where products are directly applied to the skin, mucous membranes, and other sensitive areas of the body. These products are not only intended for aesthetic enhancement but also to improve skin health and hygiene.

Given the intimate contact with the skin, ensuring microbiological safety is crucial in preventing infections, irritations, and spoilage (Antonella *et al.,* 2018). Without rigorous microbiological testing, cosmetic products can pose significant risks to consumer health, particularly for individuals with sensitive skin or underlying dermatological conditions (Sanchita *et al.,* 2017). Key microbiological tests commonly implemented in the cosmetics industry, detailed methodology, tested for, sample type, regulatory acceptance limit and Compendial References are tabulated in table 3.

Microbial Contamination Control: This testing ensures that cosmetic products, from creams to serums, are free from harmful microorganisms that could lead to infections, skin irritations, or spoilage. The test involves assessing both the finished product and the production environment to ensure microbial load remains within safe limits.

Preservative Efficacy Testing (PET): Preservatives are added to cosmetics to prevent microbial growth throughout their shelf life. PET evaluates the effectiveness of these preservatives in inhibiting the growth of bacteria, molds, and yeasts, ensuring that products remain microbiologically stable during their use by consumers.

Pathogen Detection: This test identifies harmful pathogens such as *Escherichia coli* and *Staphylococcus aureus*, which can cause skin infections and other health complications. Techniques like PCR (Polymerase Chain Reaction) or ELISA (Enzyme-Linked Immunosorbent Assay) are commonly employed for rapid and accurate detection.

Yeast and Mold Testing: Particularly relevant for natural or organic cosmetic products, this testing helps identify fungal contamination that may arise from ingredients like plant extracts, which are often more susceptible to microbial growth. Yeast and mold can spoil products and potentially cause skin irritation.

Microbial Limit Testing (MLT): This method ensures that microbial levels in cosmetic products fall within acceptable limits set by regulatory authorities like the FDA, European Medicines Agency (EMA), and other health and safety organizations. MLT is crucial for products like shampoos, lotions, and makeup products, which are frequently used and have extended shelf lives.

Antimicrobial Effectiveness Testing: In the case of products such as hand sanitizers, deodorants, and antibacterial skincare items, antimicrobial testing assesses the ability of these products to prevent the growth of harmful microorganisms. This is critical for products claiming to have antibacterial or antimicrobial properties.

Raw Material Testing: To ensure that ingredients used in cosmetic formulations are free from microbial contamination, raw material testing is conducted. This is particularly important for natural ingredients, which may carry a higher risk of contamination. Testing helps prevent the introduction of harmful microorganisms during the manufacturing process.

Table.1 Principal microbiological testing approaches used in pharmaceutical quality control, regulatory acceptance limit and Compendial References

Name of Microbial Test	Testing Method	Tested For	Sample Types	Regulatory Acceptance Limit	Compendial References	Remarks
Sterility Testing	Direct Inoculation or Membrane Filtration **Media used:** Fluid Thioglycollate Medium (FTM); Soybean-Casein Digest Medium (SCDM or TSB)	Presence or absence of viable microorganisms (bacteria, fungi) in a sterile product. **Incubation Conditions:** FTM: 30 –35°C for 14 days SCDM: 20–25°C for 14 days	Parenteral drugs, ophthalmic solutions, implantable devices, sterile APIs, and sterile excipients	No microbial growth should be observed over the 14-day incubation period	-USP <71> -Ph. Eur. 2.6.1 -JP 4.06	-Critical for sterile products; noncompliance results in batch rejection - False positives may arise from lab contamination; strict aseptic technique is required - A validated aseptic process is essential to minimize sterility testing failures
Bacterial Endotoxin Testing (BET)	Limulus Amebocyte Lysate (LAL) assay, with three main methods: 1.Gel-Clot 2.Turbidimetric (Kinetic) 3.Chromogenic (Kinetic or Endpoint)	Bacterial endotoxins - lipopolysaccharide (LPS) components from the outer membrane of Gram-negative bacteria	Injectable drugs, sterile water, medical devices (e.g., IV sets, catheters), dialysis fluids, implantable materials	Expressed as Endotoxin Units (EU)/mL or EU/device, based on dose and route of administration. Examples: - Intravenous drugs: ≤5 EU/kg/hr - Intrathecal drugs (spinal): ≤0.2 EU/kg/hr - Medical devices: depends on contact area and clinical use; e.g., <0.5 EU/mL for some devices	-USP <85> - Ph. Eur. 2.6.14 - JP 4.01	- LAL test is highly sensitive (can detect as low as 0.005 EU/mL) -False positives/negatives can occur due to product interference validation of the test (inhibition /enhancement test) is mandatory - Replaced the older rabbit pyrogen test for most products, though it is still required in some cases (e.g., for products not suitable for LAL) -Recombinant Factor C (rFC) assay is an emerging non-animal alternative gaining regulatory acceptance in some regions (e.g., Ph. Eur. 2.6.32)
Microbial Limit Testing	Plate Count Methods and Specified Microorganism Tests, as described in: -USP <61>	-Total Aerobic Microbial Count (TAMC) -Total Yeast and Mold Count	Non-sterile pharmaceutical products (e.g., oral tablets, syrups,	Varies by product category (USP <1111>, Ph. Eur. 5.1.4): Example Limits:	-USP <61> (Microbial enumeration) -USP <62> (Tests for	- Required for quality control of non-sterile products -Must be validated for sample-specific interference (inhibitory /excess microbial growth due to

	(Quantitative tests) -USP <62> (Qualitative tests for specified organisms)	(TYMC) - Presence/absence of specified objectionable microorganisms (e.g., *E. coli*, *Salmonella*, *P. aeruginosa*, *S. aureus*, *Candida albicans*, *Clostridia*)	creams), nutraceuticals, herbal preparations	- TAMC: ≤10^3 CFU/g or mL - TYMC: ≤10^2 CFU/g or mL -Specified microorganisms: Must be absent in defined quantity (e.g., *E. coli* absent in 1 g/mL, *Salmonella* absent in 10 g)	specified microorganisms) -Ph. Eur. 2.6.12 and 2.6.13	product matrix) -Selection of objectionable organisms depends on product type, use, and patient population -Water activity (aw), pH, and preservatives in the formulation may influence microbial growth potential
Antimicrobial Effectiveness Testing / Preservative Efficacy Testing (PET)	Artificially inoculate product with specified microorganisms and assess log reduction over time	Effectiveness of antimicrobial preservatives in preventing microbial proliferation during shelf life and in-use exposure	Multi-dose pharmaceutical products, topical preparations, cosmetics, personal care products, ophthalmic and otic products	USP <51> Criteria for Category 1 Products (e.g., injectables, nasal/ophthalmic solutions): - ≥1.0 log reduction by 7 days and no increase at 28 days (*S. aureus*, *E. coli*, *P. aeruginosa*) -No increase from initial count at 14 and 28 days (*C. albicans*, *A. brasiliensis*) Different categories (2–4) have less stringent requirements depending on the route and risk of use.	-USP <51> -Ph. Eur. 5.1.3 -JP Preservative Efficacy Test Guidelines	Required for multi-use products to ensure preservatives prevent microbial contamination during normal usage -Product-specific validation is essential due to potential preservative neutralization by formulation components
Pathogen Identification and Characterization	Classical Microbiological Methods (culture, Gram staining, biochemical tests) Advanced Molecular Techniques: -Polymerase Chain	Identification and classification of objectionable or pathogenic microorganisms	-Raw materials -In-process samples -Finished products - Environmental monitoring	-Specified pathogens must be absent in defined sample sizes (e.g., *Salmonella* absent in 10 g, *E. coli* absent in 1 g) - No acceptable limit for objectionable	-USP <62>: Tests for Specified Microorganisms - Ph. Eur. 2.6.13 - FDA Guidance for Industry: Microbial	- Identification is essential for root cause analysis during out-of-specification (OOS) or contamination events -Genotypic methods provide higher specificity and faster turnaround compared to classical methods

	Reaction (PCR) -16S/18S rRNA gene sequencing -Matrix-Assisted Laser Desorption Ionization-Time of Flight Mass Spectrometry (MALDI-TOF MS) -Whole Genome Sequencing (WGS) (for high-resolution strain typing)		isolates	organisms in most cases - any detection triggers investigation and corrective action	Testing of Non-Sterile Products -ICH Q6A (Specifications) and Q7 (GMP for APIs)	-Required for environmental isolates in cleanrooms (especially in ISO Class 5–7 areas) -Increasingly important in risk assessment and microbiological quality risk management (QRM) frameworks
Antibiotic Resistance Profiling	**Phenotypic Methods**: - Disk Diffusion (Kirby-Bauer) -Broth Microdilution (to determine Minimum Inhibitory Concentration – MIC) -E-test (gradient method) **Genotypic Methods**: -PCR for resistance genes (e.g., *mecA*, *bla*, *van*) -DNA microarrays -Whole Genome Sequencing (WGS) for strain-level resistance profiling	Detection of antimicrobial resistance (AMR) in microbial isolates	-Clinical pathogens - Environmental or raw material isolates - Contaminants found during manufacturing	No defined quantitative limit; however: -Resistance profiling is required when pathogens are isolated from sterile products or critical areas -Regulators expect identification and risk assessment of resistant strains found during contamination events -Critical for antibiotic manufacturing sites to ensure resistant strains are not being propagated or released	-WHO Global Action Plan on AMR -EMA: Guidelines on environmental risk assessment of medicinal products -FDA: Guidance on antimicrobial drug products and microbiological considerations -USP <1127>: Microbiological Best Laboratory Practices	- Crucial for assessing the clinical relevance of microbial contamination -Helps determine whether contamination may pose a therapeutic failure risk -In antibiotic production facilities, this testing helps prevent cross-contamination with resistant strains -Supports infection control and environmental monitoring programs -Often required in conjunction with Pathogen Identification during OOS investigations or sterilization failures

Table.2 Principal microbiological testing approaches used in nutraceutical quality control testing, regulatory acceptance limit and Compendial References

Name of Microbial Test	Testing Method	Tested For	Sample Types	Regulatory Acceptance Limit	Compendial References	Remarks
Microbial Contamination Control	Quantitative Microbial Enumeration Tests using: - Plate count methods (pour plate, spread plate) - Membrane filtration (for liquids) - Rapid methods (e.g., ATP bioluminescence, flow cytometry, PCR for total counts)	- Total Aerobic Microbial Count (TAMC): General bacterial contamination - Total Yeast and Mold Count (TYMC): Fungal contamination - Indicator organisms: May include *Bacillus*, *Coliforms*, *Enterobacteriaceae*, etc. depending on product	- Powders (e.g., protein, herbal extracts) - Tablets and capsules - Liquid supplements and functional beverages - Gel-based or oil-based formulations	Typical industry standards (may vary by region and product type): - TAMC: $\leq 10^3$ to 10^5 CFU/g or mL - TYMC: $\leq 10^2$ to 10^3 CFU/g or mL - Pathogens (e.g., *Salmonella*, *E. coli*): Must be absent in 10 g or 1 g, depending on the product	-USP <61>: Microbial Enumeration -Ph. Eur. 2.6.12 USP <1111>, FDA CFR 21 Part 111, Health Canada, EFSA, or FSSAI	- Microbial limits depend on route of administration, target population, and raw material origin (e.g., herbal vs synthetic) -Moisture, pH, and storage conditions greatly influence microbial growth risk
Pathogen Detection	Qualitative Tests for Specified Pathogens, based on: - USP <62> and Ph. Eur. 2.6.13 guidelines - Enrichment culture methods (e.g., selective broths and agars) - Molecular methods for confirmation or rapid detection: • PCR (Polymerase Chain Reaction)	Detection (presence/absence) of specified objectionable pathogens, commonly including: - *Salmonella spp.* - *Escherichia coli* (E. coli) - *Staphylococcus aureus* - *Pseudomonas aeruginosa* - *Listeria*	- Herbal supplements (capsules, tablets, extracts) - Functional foods and beverages - Protein powders and probiotics - Gummy and gel-based products	Pathogens must be ABSENT in specified sample sizes, as per regional guidelines: - *Salmonella*: Absent in 10 g or 25 g - *E. coli*: Absent in 1 g or 10 g - *S. aureus*, *P. aeruginosa*: Absent in 1 g (if tested)	USP <62>, FDA 21 CFR Part 111, EFSA, FSSAI, Health Canada	- Nutraceuticals, especially plant-based or minimally processed products, are at higher risk for pathogen contamination - Use of rapid molecular techniques (e.g., PCR) can significantly reduce detection time and improve accuracy - Testing should be part of a preventive control program (e.g., HACCP or GMP) rather than just finished-product testing - Pathogen detection is

	• qPCR (Quantitative PCR) • ELISA (Enzyme-Linked Immunosorbent Assay) • DNA sequencing (for strain confirmation)	*monocytogenes* - *Clostridium spp.* (in some cases) - *Bacillus cereus* (especially in powdered botanicals)				particularly critical for products marketed to immunocompromised or elderly consumers
Bacterial Endotoxin Testing (BET)	Limulus Amebocyte Lysate (LAL) assay, with three main methods: 1.Gel-Clot 2.Turbidimetric (Kinetic) 3.Chromogenic (Kinetic or Endpoint)	Bacterial endotoxins - lipopolysaccharide (LPS) components from the outer membrane of Gram-negative bacteria	Liquid nutraceuticals, such as injectable vitamins, oral drops, or emulsions -Protein hydrolysates, collagen products, or parenteral nutrition supplements that may contain residual endotoxins from fermentation or animal-derived raw materials	No universal limit across all nutraceuticals—limits depend on intended use and formulation. Where applicable, follow pharmaceutical standards: - For oral products: Typically ≤5 EU/kg body weight/hour, depending on product dosage and use - For parenteral-use nutraceuticals (if applicable): Must comply with USP <85> and Ph. Eur. 2.6.14 endotoxin limits	- USP <85>: Bacterial Endotoxins Test - Ph. Eur. 2.6.14 - FDA 21 CFR Part 211.167 (if injectable)	- BET is especially important for fermentation-derived, animal-derived, or injectable nutraceuticals (e.g., liposomal vitamin C, amino acid infusions) - While not mandatory for all oral supplements, risk-based approaches (HACCP, GMP) may recommend testing for products targeting sensitive populations (e.g., infants, elderly, immunocompromised) - Residual endotoxins can cause inflammatory responses, even in non-viable bacterial contaminants - Interference testing must be performed to confirm LAL reaction is not inhibited or falsely triggered by sample components (e.g., herbal extracts, sugars, proteins)
Antimicrobial Effectiveness Testing /	-Deliberate inoculation of product with a	Efficacy of preservatives in inhibiting microbial	- Liquid nutraceuticals (e.g., syrups,	USP <51> Category 2 (typical for oral	- USP <51> - Ph. Eur. 5.1.3 - ISO 11930 (for	- AET is critical for products with extended shelf life, multi-use formats, or

Preservative Efficacy Testing (PET)	defined quantity of test microorganisms - Monitor microbial log reduction over time (usually at 7, 14, and 28 days)	growth after contamination during use or storage	oral drops, vitamin shots) - Multi-dose formulations prone to contamination after opening - Gel capsules, creams, or any product with water activity (aw) > 0.6	nutraceuticals): - Bacteria: ≥2.0 log reduction at 14 days and no increase at 28 days - Fungi (yeast & mold): No increase from initial count at 14 and 28 days More stringent criteria (Category 1) may apply for sterile or high-risk products	cosmetic/nutraceutical hybrids) - FDA CFR 21 Part 111	susceptible formulations (e.g., high sugar or protein content) - The selection and concentration of preservatives must be appropriate for the product matrix (e.g., natural products may neutralize synthetic preservatives) - Some countries require AET data for registration or import approval (e.g., India, EU) - AET results can vary depending on pH, excipients, viscosity, and packaging—so testing must be done on the final formulation
Probiotics	Quantification and Characterization of Probiotics: - Plate Count Method: Most commonly used for quantifying viable probiotics (e.g., CFU/g or CFU/mL). Typically performed using selective media. - PCR (Polymerase Chain Reaction): Used for identifying specific strains of probiotics, especially when culture-based methods are not feasible.	-Viability: The number of living and active probiotic organisms that can confer health benefits. -Identity: Correct identification of the strain(s) specified on the label (e.g., *Lactobacillus rhamnosus GG*, *Bifidobacterium animalis*). -Purity: Ensuring that no unintended microorganisms are present in the product. -Stability:	-Probiotic capsules, tablets, or powders -Probiotic drinks or yogurts -Probiotic-enriched functional foods -Probiotic and synbiotic formulations	USP <2021> (for dietary supplements, includes probiotics): Recommended minimum count of viable microorganisms at the end of shelf life, often specified in CFU/g or CFU/mL. - FDA 21 CFR Part 111: No explicit numeric limits for probiotics, but products should meet label claims for probiotic	-USP <2021>: Microbiological Examination of Nonsterile Products -EFSA guidelines: European Food Safety Authority - Health Claims -Health Canada: Natural Health Products Regulations -FDA 21 CFR Part 111: Dietary Supplements Current Good Manufacturing Practices	-Storage Conditions: Probiotics are sensitive to temperature, humidity, and oxygen. Testing should evaluate storage stability under recommended conditions. -Strain-Specific Efficacy: Probiotic efficacy is strain-specific, so testing should confirm not only viability but also whether the strain used in the product is capable of providing health benefits. -Labeling: Labels must include the strain identity (e.g., *Lactobacillus acidophilus LA-5*) and CFU count at expiration, according to both regulatory guidelines

	- DNA Sequencing: Provides genetic identification of the probiotic strains. - Flow Cytometry: Used for rapid enumeration of viable probiotics. - Viable Cell Counting: Using methods like the Colony Forming Unit (CFU) count, or membrane filtration for liquid products.	Assessment of probiotic survivability over the shelf life of the product. -Potency: Testing the concentration of probiotics (measured in CFU) at the time of manufacture and at expiration.		content and identity at the time of consumption. -EFSA and Health Canada: No strict regulatory limits but require proof of identity and potency for probiotic health claims.		and best industry practices. -Probiotic products can lose viability over time, so manufacturers need to ensure products meet potency and viability claims throughout their shelf life. -Probiotic mixtures: When a product contains multiple probiotic strains, testing should assess the viability and stability of each strain individually.

Table.3 Principal microbiological testing approaches used in cosmetics quality control testing, regulatory acceptance limit and Compendial References

Name of Microbial Test	Testing Method	Tested For	Sample Types	Regulatory Acceptance Limit	Compendial References	Remarks
Microbial Contamination Control	Quantitative and Qualitative Microbial Testing, typically using: - Plate count methods (pour plate or spread plate for TAMC & TYMC) - Membrane filtration (for low-microbial-load liquids) - Rapid methods (e.g., ATP bioluminescence, flow cytometry, qPCR for verification)	- Total Aerobic Microbial Count (TAMC) - Total Yeast and Mold Count (TYMC) - Specified Pathogens, such as: • *Staphylococcus aureus* • *Pseudomonas aeruginosa* • *Escherichia coli* • *Candida albicans*	- Creams, lotions, shampoos, conditioners - Serums, gels, face masks - Decorative cosmetics (lipstick, mascara, powders) - Baby and intimate care products	ISO 17516:2014 (typical limits): - TAMC: ≤ 1000 CFU/g or mL - TYMC: ≤ 100 CFU/g or mL - Specified pathogens: Absent in 1 g or 1 mL	- ISO 17516:2014 (Cosmetics – Microbiology – Microbiological limits) - USP <61> and USP <62> (where applicable)	- Water-based and natural formulations are more prone to microbial growth, increasing the need for preservative systems and routine testing. - Although cosmetics are not sterile, good microbiological quality is essential to prevent infections, spoilage, and adverse reactions. - Routine testing of batches and raw material checks are key components of a robust quality management system.
Pathogen Detection	- Enrichment culture followed by selective agar plating - Biochemical identification (e.g., API strips) - Molecular techniques (e.g., PCR) for rapid or confirmatory detection	Specified objectionable pathogens: - *Escherichia coli* - *Staphylococcus aureus* - *Pseudomonas aeruginosa* - *Candida albicans*	- Rinse-off and leave-on products - Products used on mucous membranes (e.g., lip balm, eye cream) - Baby care, intimate care, and compromised skin products	All four specified pathogens must be absent in 1 g or 1 mL of product Some countries (e.g., EU, US, Japan) enforce stricter compliance for high-risk categories such as eye-area or infant-use products	- ISO 21150 (for *E. coli*) - ISO 22717 (for *Staphylococcus aureus*) - ISO 22718 (for *Pseudomonas aeruginosa*) - ISO 18416 (for *Candida albicans*)	- Absence of specific pathogens is critical for consumer safety, especially in products that come in contact with sensitive areas - Routine pathogen screening is part of Good Manufacturing Practice (GMP) and quality control systems - Pathogen detection should be conducted post-formulation and after packaging, as contamination often occurs during filling

						and handling - Rapid methods like PCR or immunoassays can speed up batch release but should be validated against traditional culture methods for accuracy
Antimicrobial Effectiveness Testing / Preservative Efficacy Testing (PET)	Inoculate product with known concentrations (10^5–10^6 CFU/mL) of standard microorganisms. Measure reduction in microbial counts over time (typically on Days 7, 14, and 28).	Evaluates the effectiveness of the preservative system in preventing microbial growth after contamination.	- Creams, lotions, shampoos, conditioners - Serums, emulsions, face masks - Eye-area and baby-care products	ISO 11930 Criteria (A-pass): - Bacteria: ≥3 log reduction in 7 days and no increase through Day 28 - Yeast & Mold: ≥1 log reduction in 14 days and no increase through Day 28 USP <51> (Category 2 - topical products): - Bacteria: ≥2.0 log reduction at 14 days, no increase at 28 days - Fungi: No increase at 14 and 28 days	ISO 11930: Cosmetics	- PET is mandatory for most non-sterile cosmetics, especially those containing water or with extended shelf life. - AET results guide the selection and concentration of preservatives. - Natural products and preservative-free formulations must still demonstrate microbiological stability and may require alternative preservation strategies. - Product matrix (pH, viscosity, etc.) can affect preservative activity—testing must be done on the final formulation.
Testing for Allergens and Irritants	In Vitro Testing: - Reconstructed Human Epidermis (RHE) models (e.g., EpiDerm™, SkinEthic™, EpiSkin™)	- Common allergens (e.g., fragrance allergens like linalool, limonene, eugenol, geraniol) - Irritants that cause inflammation or	- Leave-on and rinse-off cosmetics - Products intended for sensitive areas (face, eyes,	EU Cosmetic Regulation (EC No 1223/2009): - Requires labelling of 26 specific fragrance allergens if	EC No 1223/2009 U.S. FDA (under 21 CFR 701.3) IFRA Standards (International Fragrance Association)	- Allergen and irritant testing is essential to minimize adverse skin reactions and product recalls. - Animal testing is banned or restricted in many regions (e.g., EU, UK, India), so

	- Direct Peptide Reactivity Assay (DPRA) – for skin sensitization prediction - Human Cell Line Activation Test (h-CLAT) - KeratinoSens™ assay In Vivo (when in vitro is inconclusive or not validated for specific cases): - Human Repeat Insult Patch Test (HRIPT) - Modified Draize Test	discomfort (e.g., harsh surfactants, alcohols, preservatives like methylisothiazolinone) - Phototoxic substances (that react under light exposure) - Known contact sensitizers (e.g., nickel compounds, formaldehyde releasers)	mucous membranes) - Baby products, natural/organic formulations, and fragrance-containing items	concentrations exceed: • 0.001% in leave-on products • 0.01% in rinse-off products U.S. FDA (under 21 CFR 701.3): - Requires labelling of all ingredients, but does not mandate allergen-specific limits	provide usage limits and safety evaluations of fragrance ingredients	validated in vitro alternatives are preferred. - Testing must reflect actual use conditions, including exposure time, concentration, and application site.
Probiotic Cosmetics Testing	Viability and Enumeration: - Plate Count Method (CFU/g or CFU/mL): For quantifying viable probiotic organisms using selective culture media. - Flow Cytometry: Rapid detection of live vs. dead cells. - qPCR or RT-qPCR: Detects and quantifies DNA of specific strains (strain-specific identification), but does not distinguish between live and dead organisms unless coupled with viability	- Viability: Ability of probiotic strains to remain alive and active throughout the product's shelf life. - Strain Identity: Verification of the labeled probiotic strain (e.g., *Lactobacillus rhamnosus*, *Bifidobacterium bifidum*). - Purity: Absence of harmful or contaminating microorganisms. - Stability: Maintenance of probiotic activity over time in the cosmetic	- Probiotic-infused creams, lotions, serums - Face masks, emulsions, mists - "Microbiome-friendly" skincare and personal care products	- No universal regulatory limits yet established for probiotics in cosmetics - EU and ASEAN Cosmetic Regulations: Require safety and substantiation of claims - Products labeled with probiotic content must meet declared strain identity and CFU count at the end of shelf life.	-	- Live probiotics in cosmetics pose unique challenges: exposure to oxygen, preservatives, and non-ideal storage conditions can rapidly reduce viability. - Products may instead use postbiotics (inactivated bacteria or fermentation products), which are easier to stabilize but must be labeled accordingly. - Claim substantiation is critical: If claiming probiotic benefits (e.g., "balances skin microbiome"), scientific data must support both the identity and viability of the strain. - Formulators often use

	dyes (e.g., PMA-qPCR). Identity Verification: - 16S rRNA Sequencing or MALDI-TOF MS: For confirming probiotic species and strain identity. Stability Testing: - Simulated storage conditions (temperature/humidity) to monitor viability over shelf life.	formulation. - Functionality (optional): In vitro assays for benefits like anti-inflammatory or skin barrier support.				airless packaging or freeze-dried (lyophilized) probiotics to improve shelf life.

Table.4 USP in Microbial Testing and Sterility Assurance General Chapters and its brief description

S No	USP General Chapter	Name and title of the USP chapter	Description
1	USP <51>	Antimicrobial Effectiveness Testing	Evaluates the effectiveness of antimicrobial agents in pharmaceutical products to inhibit microbial growth and ensure the product's safety throughout its shelf life.
2	USP <60>	Microbiological Examination of Nonsterile Products: Tests for Burkholderia cepacia Complex	Detects the presence of Burkholderia cepacia, a group of bacteria that can be harmful, particularly to immunocompromised individuals, ensuring nonsterile products are free from this pathogen.
3	USP <61>	Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests	Determines the total microbial count (including bacteria, yeast, and molds) in nonsterile products, ensuring they are microbiologically safe for use.
4	USP <62>	Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms	Tests nonsterile products for specific harmful microorganisms (e.g., Salmonella, E. coli, Pseudomonas aeruginosa) to ensure the product is free from pathogenic contamination.
5	USP <63>	Mycoplasma Tests	Detects Mycoplasma contamination in biologic products like vaccines and cell cultures, as Mycoplasma can be challenging to detect and can interfere with cell-based therapies.
6	USP <64>	Probiotic Tests	Verifies the identity, potency, and purity of probiotic products, ensuring they contain the correct strains and are free from harmful microorganisms.
7	USP <71>	Sterility Tests	Confirms that sterile products (such as injectables and ophthalmic solutions) are free from viable microorganisms, ensuring their safety for patient use
8	USP <72>	Respiration-Based Microbiological Methods for the Detection of Contamination in Short-Life Products (Effective 01-Aug-2025)	Uses respiration-based methods (oxygen consumption or carbon dioxide production) to detect microbial contamination in short-life products, like food and biologics.
9	USP <73>	ATP Bioluminescence-Based Microbiological Methods for the Detection of Contamination in Short-Life Products (Effective 01-Aug-2025)	Detects microbial contamination in short-life products using ATP bioluminescence, which measures light emitted from the ATP reaction, indicating microbial presence.
10	USP <85>	Bacterial Endotoxins Test	Detects endotoxins (toxins from bacterial cell walls) in pharmaceuticals and medical devices, as these toxins can cause severe health reactions such as fever and shock in patients.
11	USP <86>	Bacterial Endotoxins Test Using Recombinant Reagents (Effective 01-May-2025)	Provides an alternative method for endotoxin testing using recombinant reagents (instead of traditional horseshoe crab-derived reagents), promoting sustainability and ethical sourcing.
12	USP <797>	Pharmaceutical Compounding—Sterile Preparations	Offers guidelines for aseptic techniques and microbiological safety in the compounding of sterile products, ensuring their sterility and quality.
13	USP <1071>	Rapid Microbiological Methods for the Detection of Contamination in Short-Life Products – A Risk-Based Approach	Introduces a risk-based approach to using rapid microbiological methods (RMMs) for the quick detection of microbial contamination in short-life products.

14	USP <1072>	Disinfectants and Antiseptics	Tests the efficacy of disinfectants and antiseptics in killing or inhibiting harmful microorganisms, preventing contamination in healthcare and pharmaceutical environments.
15	USP <1110>	Microbial Contamination Control Strategy Considerations (Not Official, open for comment through May 31, 2025)	Provides guidance for companies to develop microbial contamination control strategies to minimize microbial risks during pharmaceutical manufacturing.
16	USP <1111>	Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use	Defines the microbiological acceptance criteria for nonsterile pharmaceutical preparations, ensuring their safety for patient use.
17	USP <1114>	Microbial Contamination Control Strategies for Cell Therapy Products (Not Official, open for comment through May 31, 2025)	Offers guidance on controlling microbial contamination during the processing and handling of cell therapy products, which are highly sensitive to microbial contamination.
18	USP <1115>	Bioburden Control of Nonsterile Drug Substances and Products	Ensures control over bioburden (microbial contamination) during the manufacturing of nonsterile drug substances, minimizing contamination risks in the final product.
19	USP <1116>	Microbiological Control and Monitoring of Aseptic Processing Environments	Establishes guidelines for microbiological control and monitoring in aseptic processing environments to prevent contamination of sterile products during manufacturing.
20	USP <1120>	Ensuring Microbiological Quality of Articles of Botanical Origin (To be Official)	Ensures the microbiological quality of botanical products (e.g., herbal medicines) by testing for microbial contamination that could compromise the product's safety.
21	USP <1227>	Validation of Microbial Recovery from Pharmacopeial Articles	Validates methods for recovering microorganisms from pharmacopeial articles, ensuring accurate microbial testing during product evaluation.
22	USP <1231>	Water for Pharmaceutical Purposes	Sets standards for the microbiological quality of water used in pharmaceutical manufacturing, ensuring it meets purity criteria to avoid contamination in drug products.
23	USP <2021>	Microbial Enumeration Tests—Nutritional and Dietary Supplements	Tests nutritional and dietary supplements for total microbial count (bacteria, yeast, molds), ensuring these products are microbiologically safe for consumption.
24	USP <2022>	Microbiological Procedures for Absence of Specified Microorganisms - Nutritional and Dietary Supplements	Ensures that nutritional and dietary supplements are free from specific harmful microorganisms (e.g., Salmonella, E. coli), preventing illness from contaminated products.

Testing for Allergens and Irritants: While not strictly a microbiological test, this testing ensures that products do not contain substances that could trigger allergic reactions or irritation in sensitive individuals. Many cosmetics include testing for common allergens such as fragrances, preservatives, and plant-based ingredients.
Probiotic Cosmetics Testing: With the growing trend of **probiotic skincare products**, testing ensures that beneficial microorganisms added to cosmetics remain viable and effective throughout the product's shelf life. These probiotics are designed to improve the skin's microbiome and offer anti-inflammatory benefits, but their effectiveness depends on their survival and activity in the final formulation.

The Role of USP in Microbial Testing and Sterility Assurance

The United States Pharmacopeia (USP) is a science-based public standards-setting globally recognized organization that plays a critical role in ensuring the quality, safety, and efficacy of medicines, dietary supplements, related products, particularly in pharmaceuticals, biotechnology, and medical devices. One of its central contributions is the development of comprehensive guidelines for microbiological testing and sterility assurance**,** which are essential components of product quality control (Rehan *et al.,* 2024).

Microbiological Testing Standards

The USP provides detailed microbiological testing protocols in several chapters of its compendium, categorized as General Chapters**.** These chapters are widely adopted in regulatory frameworks and manufacturing quality systems globally. The most relevant chapters and details are tabulated in table 4.

Microbiological testing plays a critical role in safeguarding the safety, quality, and efficacy of pharmaceutical, nutraceutical, and cosmetic products. Given the potential health risks associated with microbial contamination particularly for immunocompromised individuals rigorous testing protocols are essential across all stages of production and distribution. International regulatory bodies such as the USP, FDA, and EMA have established stringent guidelines that govern testing methodologies and permissible microbial limits for different product categories. Core procedures, including sterility testing, microbial limit tests, endotoxin assessment, and environmental monitoring, serve as foundational pillars in maintaining product integrity and consumer safety. As regulatory demands intensify and consumers become increasingly vigilant about product safety, the importance of comprehensive microbiological testing continues to grow. Consistent adherence to validated testing standards not only ensures public health protection but also reinforces consumer confidence and supports long-term industry sustainability.

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Sricharan Gumudavelli: Investigation, formal analysis, writing—original draft. G. Srinija: Validation, methodology, writing—reviewing. Chinna Reddy Palem:—Formal analysis, writing—review and editing.

Data Availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical Approval Not applicable.

Consent to Participate Not applicable.

Consent to Publish Not applicable.

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