

Microbiology 301 Guide

This guide covers the critical steps of microbiology testing, common test methods, and the importance of microbial suitability.

Primary Stages When Cosmetic Microbiology Testing Is Performed

Microbiology testing is performed at multiple stages to help ensure quality and safety:

Water: Whether used in the formulation or manufacturing process, it is one of the most common sources of contamination in cosmetics.

Bulk/In-Process: During mixing or compounding phases.

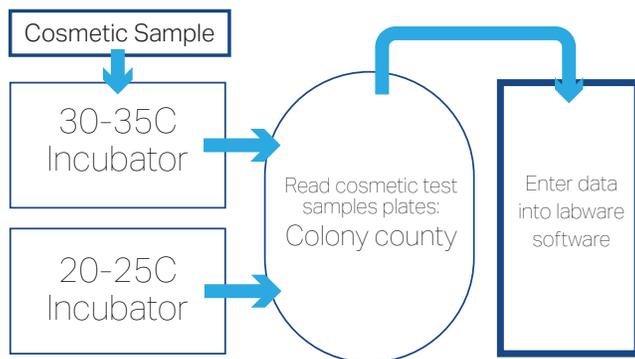
Finished Product: Before it's released to market.

Raw Ingredients: Especially botanical or natural materials.

Key Micro Testing Steps

1. Receive samples in the lab using aseptic techniques to ensure sample integrity.
2. Neutralize product in nutrient broth.
3. Transfer into petri dishes and add agars.
4. Incubate: 30° to 35°C (3 days) - TAPC.
5. Incubate: 20° to 25°C (5 to 7 days) - TYMC.
6. Perform enrichment step.
7. Read plates: using colony counter with light source and magnifying glass, look for bacteria growth on tryptic soy agar (TSA) plates. Look for yeast/mold growth on potato dextrose agar (PDA)/(SDA) plates.
8. Following Standard Operating Procedure (SOP), enumerate any microbial growth and characterize any potentially pathogenic microorganisms (e.g. *Staphylococcus aureus*).
9. Enter data into the LIMS systems.
10. Review, release Certificate of Analysis (COA) (summary of data) to customer.

Micro - Common Tests



- Pathogen Screening (e.g., *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *E. coli*, *Candida albicans*, BTGN [quantitative/qualitative], *Salmonella*, *Clostridium* (upon request))
- *Burkholderia cepacia* complex (BCC) (USP 60)
- Standards Referenced: USP 60/61/62, ISO 17516
- Total Aerobic Microbial Count (TAMC or (APC)
- Total Yeast and Mold Count (TYMC or Y/M)

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Microbial Suitability vs. Routine Testing

Microbial Suitability Testing

- Purpose: Proves the test method works with your product
- Validates the method for your specific formula
- Confirms microbes can be recovered from the product
- Ensures preservatives or ingredients don't interfere with detection
- Typically performed once per new formulation

Key takeaway: Proves the test works

Routine Microbiological Testing

- Purpose: Checks if microbes are present
- Evaluates the product itself
- Measures microbial counts or detects specified organisms
- Confirms compliance with microbial limits
- Performed on production batches as needed

Key takeaway: Tests the product

The importance of micro suitability

Ensures Method Validity

- Needed for any new product or formulation (typically required once).
 - Adding an active, fragrance, or color makes a formula "new," as these changes can impact microbial growth and preservative performance.
- Suitability testing verifies that the microbiological method can accurately detect microbes in your specific product.
- Many cosmetic or OTC formulations contain preservatives, high salt or sugar levels, or other ingredients that can inhibit microbial recovery. If recovery is not verified, a "clean" result may not reflect the true microbial risk.

Regulatory Requirement

- USP <61/62> (microbial enumeration and qualitative tests for specified organisms) and USP 60 (*Burkholderia cepacia* complex) require suitability testing as part of compliance.



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