

# Microbiology

## Basic FAQ Guide

Commonly asked questions about microbiology testing for cosmetics, OTC drugs, and personal care products.

### 1. Which products need microbiology testing?

Most water-containing cosmetics, personal care products, and topical OTC drugs require microbiology testing to ensure they do not contain harmful microorganisms and remain safe during shelf life.

### 2. Why is microbiology testing required?

Microbiology testing helps verify the absence of microorganisms that could cause infections, spoilage, recalls, or regulatory enforcement. It also supports product quality and brand protection.

### 3. What types of microbiology tests are commonly performed?

Common tests include Total Aerobic Microbial Count, Total Yeast and Mold Count, pathogen testing, and preservative challenge testing.

### 4. What are "objectionable organisms"?

They are specific bacteria that must not be present in certain products due to safety risk, such as *Salmonella*, *Candida albicans*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *E. coli*, and *Burkholderia cepacia* complex.

### 5. What is preservative challenge testing (USP<51>)?

This test evaluates whether a product's preservative system can control microbial growth and resist contamination during consumer use.

### 6. When should microbiology testing be performed?

Testing is typically done before product launch and repeated if the formula, packaging, or manufacturing process changes. Ongoing testing may also be part of quality monitoring programs.

### 7. Where is microbiology testing performed?

At ISO 17025-accredited laboratories that use validated methods such as USP and ISO standards and employ trained analyst.

### 8. How are test results used?

Results confirm whether a product meets microbial acceptance limits and regulatory expectations. Passing results support product release, while failures require investigation and corrective action.

### 9. Is microbiology testing required by FDA?

FDA expects products to be safe and free from harmful microorganisms. Testing is considered an industry best practice and is often cited in FDA enforcement actions.



Find More Answers in Our Resource Library

[CERTIFIED-LABORATORIES.COM/RESOURCE-LIBRARY/](https://www.certified-laboratories.com/resource-library/)