Microbiology 201 Guide

Microbiology testing confirms that products remain safe and free from harmful microorganisms. This guide explains how testing is performed in the laboratory and why proper methods are essential for reliable results.

What does microbiology testing evaluate?

- Total bacterial levels.
- Total yeast and mold levels.
- Absence of objectionable organisms.
- Preservative control.

Overview of the laboratory process

Microbiology testing follows a controlled workflow:

- Sample preparation
- Neutralization and dilution
- Plating or enrichment
- Incubation
- Colony counting and identification
- Result interpretation

Note: Suitability is required prior to testing and is a one-time test per formulation. Additional TAT may apply.

Sample preparation

Samples are weighed or measured and mixed with sterile diluent to release microorganisms from the product. Preservatives must be neutralized so microorganisms can survive during testing.

Neutralization and dilution

Neutralizers inhibit preservative activity. Serial dilutions prevent overcrowding of colonies and allow accurate counting.

Plating and enrichment

- **Direct plating**: Sample is applied to agar to grow colonies.
- **Enrichment**: Sample is incubated in liquid broth to encourage growth of low-level organisms before plating. Commonly used for objectionable organism testing.

Culture media selection

Different media are used for different purposes:

- General media for total bacteria.
- Fungal media for yeast and mold.
- Selective media for specific pathogens.
- Differential media for organism identification.
- Media choice affects detection accuracy.

Incubation conditions

Plates are incubated under controlled temperature and time conditions. Bacteria and fungi require different environments to grow properly. Incorrect incubation can lead to false results.

Incubation time and turnaround time

Incubation time directly determines laboratory turnaround time.

Typical ranges:

- **Bacteria**: 2–3 days
- **Yeast and mold**: 5–7 days
- **Objectionable organisms**: 3–5 days

Shorter times may miss slow-growing organisms. Longer times increase confidence but extend reporting.

Colony observation and identification

Colonies are counted and evaluated for appearance. Suspect colonies are confirmed using additional identification methods. Results are reported as CFU per gram or milliliter.

Validated methods

Testing must follow validated USP or ISO methods proven suitable for the specific product type. Validation ensures preservatives, viscosity, or oils do not interfere with microbial recovery.

Why formulation matters

Surfactants, oils, powders, and thick formulas can hide or damage microorganisms during testing. Method suitability confirms accurate recovery.

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