DYNALABS
Quality Assured™

Antimicrobial Effectiveness Testing

DYNALABS is continuously investing in our testing methods, environments and procedures.

Our commitment is to patient safety.

Antimicrobial Effectiveness testing is usually performed for aqueous pharmaceuticals that contain preservative substances in non-sterile products or sterile multi-dose containers. The challenge organisms used in this type of test are based on potential contaminants that can come from formulation, production and intended use.

To test per USP 51 requirements, each final product must undergo a Suitability to prove the test method Antimicrobial Effectiveness Method Suitability requires a formula of the product so that appropriate materials, or neutralizers, can be determined for use within the test. A Method Suitability test passes when we are able to obtain suitable recovery of all challenge organisms.

Routine testing varies according to the type of product in which a preservative is used. Compendial products are split into four different categories based on Table 1 from USP.

Table 1. Compendial Product Categories

Category	Product Description
1	Injections; other parenterals including emulsions, otic products, sterile nasal products, and ophthalmic products made with aqueous bases or vehicles
2	Topically used products made with aqueous bases or vehicles; nonsterile nasal products and emulsions, including those applied to mucous membranes
3	Oral products other than antacids, made with aqueous bases or vehicles
4	Antacids made with an aqueous base

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***DYNALABS** is the only analytical testing lab services company that helps hospital and compound pharmacies, as well as outsourcing facilities, achieve – and surpass – their goals for patient safety.*

A product from any of these categories is inoculated at day 0 and remains on test for 28 days; during which it is sampled, diluted and plated at intervals specific to each category. Counts from each of these intervals are then compared to the criteria outlined in USP Table 3, below. from USP. A sample passes if the count for each of the challenge organisms used in the test meets the requirements specified for its category.

Table 3. Criteria for Tested Microorganisms

For Category 1 Products	
Bacteria	NLT 1.0 log reduction from the initial calculated count at 7 days, NLT 3.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days
Yeast and molds	No increase from the initial calculated count at 7, 14, and 28 days
For Category 2 Products	
Bacteria	NLT 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days
Yeast and molds	No increase from the initial calculated count at 14 and 28 days
For Category 3 Products	
Bacteria	NLT 1.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days
Yeast and molds	No increase from the initial calculated count at 14 and 28 days
For Category 4 Products	
Bacteria, yeast, and molds	No increase from the initial calculated count at 14 and 28 days