



Antibiotic Microbial Testing

The antimicrobial activity test is a complex, time-sensitive set of critical tests designed to determine the level of biological activity possessed by the preservative system of a pharmaceutical product. Adequate preservation should prevent or inhibit the growth of microorganisms that may pose a risk of infection to the user or result in product degradation.¹ The activity (potency) of antibiotics may be demonstrated under suitable conditions by their inhibitory effect on microorganisms. A reduction in antimicrobial activity will also reveal subtle changes not demonstrable by chemical methods. Accordingly, microbial or biological assays remain generally the standard for resolving doubt with respect to possible loss of activity.²

What Products Should be Tested?

Sterile products presented for use in multi-dose containers and non-sterile dosage forms, particularly those intended for multiple use, are required to be tested.

- Final products
- Raw material

When Should Testing be Performed?

During product development, the stability of the preservative throughout the product's closed shelf-life and antimicrobial efficacy throughout the open shelf-life should both be established. This is established via in-process sampling and final product release testing.

Your
partner for
critical testing in
microbiology

¹ TGA - Therapeutic Goods Administration. Preservative efficacy in multidose pharmaceutical preparations. (May 1999). Retrieved May 10, 2006, from The Australian Government. Department of Health and Ageing Therapeutic Goods Administration website: <http://www.tga.gov.au/docs/html/tganews/news29/lab.htm#preserv>
² USP. USP 29-NF 24. General Chapters: <81> Antibiotics-Microbial Assays. 2006.

Study Design

Assay consists of the cylinder plate method using a specific test organism and USP reference solution. This method depends upon diffusion of antibiotic from a vertical cylinder through a solidified agar layer in a petri dish to an extent such that growth of the added microorganism is prevented entirely in a circular area or "zone" around the cylinder containing a solution of the antibiotic. The product will be tested against a reference concentration (S3). Test will be performed in duplicate on two different days.

Assay Duration: 5 days

Sample Requirement: Dependent on customer supplied product

Regulatory Compliance

- United States Pharmacopeia <81> Antibiotics – Microbial Assay

Note: Before the test is performed, trial studies are conducted to determine the appropriateness of USP method described in the USP, and will be modified if necessary.

Final Report

MicroSafe Services from Millipore can provide each client with the following final reports:

- GLP report that includes all raw data, protocol methods and final result.
- GMP report that includes a certificate of results.

Custom Assays

We understand that no production plant is identical and that every process is unique. Using a combination of practical experience and a scientific approach, we will customize antibiotic microbial testing methods to meet your specific requirements including scientifically sound data that will be accepted by regulatory authorities around the globe.

Your Partner in Microbiology

MicroSafe Services from Millipore delivers a complete range of critical testing and consultancy services for the development and production of biopharmaceuticals. Leaders in the field of microbiology including *in vitro* virology testing, our staff of accomplished scientists, engineers and microbiologists will help you meet your specific critical testing requirements throughout every phase of drug production. All testing is conducted under GMP and/or GLP certifications as well as our own internal quality system.

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For more information on our critical support services, please contact Millipore at:

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