

Antimicrobial *In-Vitro* Testing for Medical Devices

WuXi AppTec offers the following assays to determine the antimicrobial activity of medical devices, components or other materials treated with antimicrobial agents.

Any of the standard test methods listed here can be modified to include different/additional organisms as well as different/additional exposure times.



WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

**WX
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NYSE**

USP <51>, Antimicrobial Effectiveness Test

Determines the effectiveness of antimicrobial (preservative) substances for the following products: injections and other parenterals including emulsions, otic products, sterile nasal products and ophthalmic products made with aqueous bases or vehicles; topically used products made with aqueous bases or vehicles, nonsterile nasal products, and emulsions, including those applied to mucous membranes; oral products other than antacids, made with aqueous bases or vehicles; antacids made with an aqueous base. Typically conducted prior to conducting microbial recovery assays involving products with potential inhibitory or microbicidal activity.

USP <1227>, Neutralization Validation

Evaluates the method chosen to neutralize the antimicrobial properties of any product with inhibitory or microbicidal activity. Purpose of the assay is to ensure validity of test results achieved during the USP Antimicrobial Effectiveness Test and other microbial recovery tests. Conducted prior to estimating the number of viable microorganisms.

JIS Z 2801 / ISO 22196

Specifies testing methods to evaluate antimicrobial activity and antimicrobial efficacy of bacteria on the surface of antimicrobial products. Recommended test organisms are *Staphylococcus aureus* and *Escherichia coli*.

Zone of Inhibition

Demonstrates activity/potency of antimicrobials or antibiotics, based on measuring zone of inhibition observed for specified microorganisms. Areas of particular application include materials treated or infused with an antimicrobial agent that leaches out of the material.

ASTM E-2149, Dynamic Contact

Quantitatively evaluates the effectiveness of a sample treated with a non-leaching antimicrobial by shaking in an organism suspension. The typical challenge organism is *Escherichia coli*.

ASTM E-1153, Sanitizer Efficacy

Determines the efficacy of sanitizing agents on various inanimate surfaces, such as counters, floors and other areas/materials that are routinely cleaned. Typically conducted to validate sanitizing procedures for cleanrooms or aseptic processing areas.

ASTM E-2315, Time-Kill Procedure

Quantitatively evaluates the changes of a population of microorganisms within a specified sampling time when exposed to a test material or a dilution of the test material. Time points may be selected based on intended use of the material or over a longer period of time to develop a kill model for the material. Challenge organisms may be standardized strains or representative of microorganisms encountered under test material use.

ASTM E-2180

Quantitatively evaluates the effectiveness of an antimicrobial agent incorporated into hydrophobic polymeric material. Recommended challenge organisms are *Staphylococcus aureus* and *Pseudomonas aeruginosa* (or *Klebsiella pneumoniae*).

CUSTOM ANTIMICROBIAL STUDIES

With years of experience conducting microbiology/microbial testing and a laboratory dedicated to performing custom microbial studies, we offer clients extensive expertise in developing custom protocols to meet specific needs.

Antimicrobial Efficacy *In Vivo*

Specifically designed tests using animal models for AME efficacy of devices are available, such as:

- **Cardiology** – pacing device coverings and coatings
- **Neurology** – stimulation device coverings and coatings
- **General Surgery** – polymer meshes
- **Cranial Surgery** – hydrogels
- **Orthopedic** – polymeric drug delivery systems

For more information on AME studies, contact a WuXi AppTec Account Manager.

For more information on WuXi AppTec's services please contact:

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