WAY 17

ARL Bio Pharma Three Sterility Testing Options, One Standard of Excellence

Get sterility test results in as little as four hours with rapid test methods.

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Company Background

ARL Bio Pharma is a contract laboratory that provides analytical and microbiological testing for health-system pharmacies. Since 1998, ARL has supported the industry-wide commitment to deliver high-quality drug products by providing guidance and test services for all phases of the product lifecycle following USP and FDA guidelines. ARL is ISO 17025:2017 accredited, FDA-registered and audited, and DEA licensed for Schedules I through V.

Sterility Testing

Sterility testing of compounded sterile preparations is crucial to prevent patient harm from microbial contamination. USP <797> requires sterility testing for:

- Category 2 CSPs which are assigned a beyond use date (BUD) that requires sterility testing.
- All category 3 CSPs.

The Food and Drug Administration (FDA) requires 503B outsourcing facilities to perform sterility testing for all drugs reported to be sterile and/or non-pyrogenic.

Sterility testing must be performed according to USP <71> or a validated alternative method per USP <1223> that is noninferior to USP <71>. Method suitability must be demonstrated for each drug product with correct sample quantities tested according to the chapter. Sterility failures must be investigated and include the identification of contaminating microorganism(s) with documentation of the investigation and corrective action.

USP <71> Sterility Test Method: 14-18 Day Turnaround

This sterility method is a growth based test method that requires at least 14 days incubation time for microorganism growth to occur. ARL uses either a closed membrane filtration method (the preferred method) or a direct inoculation method for unfilterable sample types. At the conclusion of the test, if there is no evidence of growth, the drug product complies with the USP <71> test for sterility.

Alternative Sterility Test Methods

Rapid sterility testing allows for shortened incubation times compared to the traditional sterility test method. By reducing sterility test wait times, rapid sterility methods offer many supply chain advantages, faster product release schedules, and quick contamination investigations.

Celsis ATP Bioluminescence Method: 6 Day Turnaround

This growth-based sterility test detects microbial contamination based on the presence of microbial Adenosine Triphosphate (ATP) in a sample. Results are objective and based on instrument analysis.

ScanRDI Solid Phase Cytometry Method: 1-3 Day Turnaround

This non-growth-based sterility test detects microbial contamination based on cytometry, which detects and quantifies microorganisms in as little as four hours.

USP <1223> Method Validation

ARL's rapid sterility validation protocol includes all required parameters listed in USP <1223> including specificity, limit of detection, repeatability, and equivalency. For the growth-based method, the recovery of stressed/injured microorganisms is also assessed, which is considered imperative as injured microorganisms are more representative of potential contaminants that may be present in preparations tested.

Ordering Information

Request a Quote: info@arlok.com
ARL Bio Pharma Client Portal: portal.arlok.com

ARL's client portal allows users to submit samples online, receive test results in real-time, and analyze test data trends.