

Sterility Testing Using Isolator Technology

WuXi AppTec offers isolator technology for sterility testing of biologics and pharmaceuticals. Isolator-based sterility testing significantly reduces the probability of false positives thus providing additional assurance for your critical clinical and commercial production lots. Regulatory agencies favor using state-of-the-art technologies and systems that are best at reducing risk. Isolator technology does just that.

Advantages of Isolator Technology

- Significantly reduces likelihood of false positives
- Exceeds the cGMP requirements of ISO class 5
- Complete product/operator protection
- Sterilization of container/closure exterior vs. sanitization methods

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.

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Isolator Technology Utilization At WuXi AppTec

The IsoTech Design IsoSphere™-ST isolator is designed to allow operators to perform sterility testing in an aseptic environment, thus providing an additional level of assurance and reducing the risk of contamination, which could lead to false positives. The WuXi AppTec isolator decontamination (sterilization) process was validated using vaporous hydrogen peroxide (VHP), which is produced by a Steris VHP® 100P Biodecontamination System. VHP sterilizes the interior of the isolator and all surfaces, including the packaging/container/closures to be tested, without affecting the interior contents (the product).

Sterility testing within the isolator is performed by direct immersion or membrane filtration. The membrane filtration testing system is conducted using the Millipore Steritest™ Integral 316 system, which is integrated into the floor of the isolator.

Requirements for Isolator-Based Sterility Testing

The typical products that can be tested are contained in ampoules, vials, pre-filled syringes and bottles. Other packaging considerations can be discussed on a case-by-case basis. WuXi AppTec recommends qualifying your packaging or container/closure to ensure the integrity of your product during the VHP sterilization process prior to initiating testing of production lots. All other sterility testing guidelines (e.g., USP/EP/JP) are applicable when performing sterility testing within an isolator. WuXi AppTec's experts will work closely with you to determine if your container/closure or package will require additional qualification work.



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

U.S.
+1 (651) 675 2000 • +1 (888) 794 0077
info@wuxiapptec.com

www.wuxiapptec.com
www.virologyexperts.com