

Sterility Testing Using Isolators

Lancaster Laboratories' Pharmaceutical Microbiology Group offers sterility testing using isolator technology. The most advanced system available for sterility testing, isolator technology greatly reduces the risk of contamination during testing (false positives). We provide this service for pharmaceutical manufacturers who must demonstrate the sterility of their pharmacopeial articles. Some features of our sterility testing program are:



- Testing Facility—Our sterility tests are performed in a la Calhene soft-wall isolator system consisting of four transfer isolators, two two-half-suit workstations and an autoclave interface isolator. Three Steris VHP® 1000 systems are used for decontamination and Millipore Integral Steritest™ systems are used for membrane filtration.
- Training—Our staff is trained and certified in proper analytical techniques and GMP requirements and must pass qualification testing before performing analyses.
- Methods—We offer a full range of methods, including:
 - Membrane filtration.
 - Direct transfer.
- Quality Assurance—Each step of our sterility test program is fully QC supported:
 - Our isolator system is fully validated.
 - Growth promotion and sterility testing are performed on each lot of media.
 - A manipulative control is analyzed with each sample batch.
 - Environmental monitoring is performed with each sample batch.
 - Quality assurance audits are performed regularly.

For more information on our isolator sterility testing capabilities or any of our pharmaceutical capabilities, please contact your project manager or Pharmaceutical Business Development at 717-656-2300.



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