Compounder's International
Analytical Laboratory
Better Quality Through Quality Testing

800.788.9922
compounderslab.com

Sterility Testing Excellence

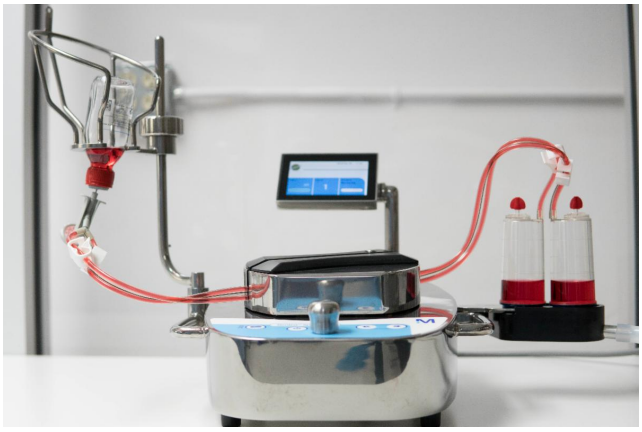
For compounding pharmacies and outsourcing facilities that produce sterile products, testing to assure that sterility has been achieved is of utmost importance. It is also the primary focus of current FDA and many state pharmacy board inspections. In addition, the newly released proposed USP General Chapter <797> allows for much longer default BUDs when sterility testing has been performed with passing results. While some pharmacies perform their own testing, regulatory agencies, both state and federal, often prefer testing performed by an independent testing laboratory.

Full Service Laboratory

Here at CIAL, we have a complete microbiology department which performs the vast majority of sterility-related testing required by 503A and 503B pharmacies. These include:

- Sterility Testing USP <71>
- Sterility Method Suitability USP <71>
- Endotoxin Testing USP <85>
- Testing specifically for Fungi/Mold/Yeast USP <71>
- Antimicrobial Effectiveness Testing USP <51>
- Microbial Enumeration of Nonsterile Products USP <61>
- Test for Specified Microorganisms in Nonsterile Products USP <62>
- Water Activity Testing USP <1112>
- Container Closure Integrity Testing USP <381>
- Visible Particulates Testing USP <790>
- Subvisible Particulate Testing USP <788> <789>
- Microscopic Examination of Unknown Substances

We Exceed Requirements



Our sterility testing area is ISO 5 within an ISO 7, accessed through an ISO 8 anteroom, which is entered from within a dedicated room having a filtered air supply. In other words, the area where we test your products meets the same requirements as the requirements listed in USP <797> for sterile product production. We perform daily cleaning of our testing areas and clean between each sample. We completely sanitize our testing area daily and carry out routine environmental monitoring. This ensures testing areas remain sterile throughout the testing process., We sanitize the inside of our Isolators between samples to maintain a gold standard sterile environment. Moreover, the items we test remain within a fully enclosed filtration and rinse system. This eliminates exposure to air, leaving your samples free from contamination during testing. Shown here is our Millipore Steritest Symbio system which provides the preferred filtration method of trapping, concentrating, and rinsing the sample of all interferences prior to incubation. These precautions give CIAL a history of no contamination incidents!

Our sterility testing process follows USP <71> explicitly

Filterable samples are passed through sterile 0.2 µm or 0.45µm filters which capture viable microbes on their surfaces. Substances that might interfere with the test, such as oil, antimicrobial agents, antibiotics, preservatives, salts, etc. are rinsed away from the filter using the appropriate rinse fluid. This leaves any microbes that might be present, free to grow unrestrained. Filters are then immersed in two ideal growth media, Tryptic Soy Broth (TSB) and Fluid Thioglycollate Media (FTM), and incubated at optimal temperatures to encourage growth. One (TSB) is incubated under aerobic conditions and the other (FTM) under anaerobic conditions. Any type of microbe, which may be present, will grow and will be detected if the original product was not sterile. Each day the growth media is visually inspected for growth, which would be indicated by the presence of turbidity. Non-filterable samples (such as suspensions) are treated similarly, but they are directly injected into specially-made containers of the same two growth media and incubated and monitored for growth.

- We use only top-of-the-line instrumentation and equipment. Our procedures and methods are performed at peak efficiency to obtain highly accurate and reliable results.
- We can test any dosage form for sterility, including API powders.
- We are proud to have developed a uniquely effective process to test pellets! We outpace the competition in the accuracy of pellet test results.
- We know it is important to receive test results as quickly as possible, so we always endeavor to begin sterility testing the same day samples are received.
- We perform daily incubator checks of every sample to ensure that an unexpected event is handled promptly and efficiently.
- We hold ourselves to the highest standards, (using isolators, exceeding requirements for cleaning, performing multiple PPE changes daily, performing calibration checks, obtaining certifications, and more) to ensure the highest quality testing results.
- Our analysts are regularly trained and certified on leading-edge procedures and regulations.
- Our test reports pass a strict, multi-level, multi-person review before we release them. This gives you complete confidence in the accuracy of your results.
- Our people are highly knowledgeable, having many years of microbiological experience.
- We provide honest guidance in helping clients meet testing requirements without encouraging unnecessary tests.

Give Us A Try

We think you will find working with us a refreshing experience! We are centrally located in the US (Colorado) so samples can easily be shipped to us overnight from where ever you are located.

We look forward to working with you!

Ronald Sutton, President

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