



MICROBIAL SOLUTIONS

Microbial Solutions for Compounding Pharmacists

United States

- USP Chapter <795>: Pharmaceutical Compounding: Non-Sterile Preparations
- USP Chapter <797>: Pharmaceutical Compounding: Sterile Preparations
- 21 USC § 353a: Pharmacy Compounding
- USP <1116>
- Sterility—USP <71>
- Bioburden—USP <61>

Europe

- EN ISO 14644-1
- Germany: Apothekenbetriebsverordnung
- Sterility—EP 2.6.1
- Bioburden—EP 2.6.12

Pharmacies that prepare individualized dosages of sterile, high-risk drugs for patients must meet stringent requirements and standards to assure patient safety. Because aseptically compounded preparations are often administered to immunocompromised individuals, proactive quality control is critical to ensuring that a bad product does not transfer risk to the patient. Charles River offers FDA-licensed products and cGMP-compliant services to maintain control and consistency in the compounding process, from in-process testing to batch release.

Relevant Guidelines and Regulations

With compounding pharmacy regulations under scrutiny, compliance has never been more important. Charles River is an ideal partner in bringing your operations in line with current regulatory standards. Paired with our method development and training support, our services reinforce the integrity of your QC program and position you to showcase your commitment to safety. By investing in the security of your compounding environment, you can continue to serve patients while being prepared to meet the highest standards, whatever regulatory shifts may come.

Bacterial Endotoxin Testing (BET)

The BETs detects unsafe levels of microbial cell wall debris from live or dead Gram-negative bacteria that cause fever and symptoms of septic shock. Until now, BET required skilled analysts and manipulation of cumbersome reagents.

The Endosafe® nexgen-PTS™ is a handheld spectrophotometer that utilizes FDA-licensed LAL cartridges to deliver accurate, real-time endotoxin results in 15 minutes at the point of sample collection. The USP/BET compliant cartridges require no microbiology training, eliminate the need to prepare endotoxin standards and are compatible with suitable dilutions of all common compounded sterile products. This rapid, on-site solution eliminates bottlenecks, improves sample management, and, most importantly, assures that products are free of endotoxin (pyrogen) within limits set by the Pharmacopeia.

To ensure that our clients get the most out of the Endosafe® nexgen-PTS™, Charles River offers additional support through method development and training.

EVERY STEP OF THE WAY

Microbial Identification for Environmental Monitoring Programs

Confident microbial and particle measurement is critical for an environmental monitoring program to ultimately confirm the security of the compounding area. Accurately identifying an organism to the species, and many times, to the strain level, facilitates tracking of the potential origin of the contamination and prevents delays in product release and completion of investigations.

Charles River offers comprehensive contract microbial testing services from our FDA-registered, cGMP-compliant laboratories. We have supported QC testing for over 1,000 global facilities within the biopharmaceutical, medical device, and nutraceutical industries with our Accugenix® bacterial/fungal identification and strain typing services. Offering a 98% accurate identification rate and 99% on-time delivery, we have tested and identified more microorganisms than any other company or service laboratory in the industry.

Sterility Testing

Sterility testing is used to demonstrate the presence or absence of extraneous viable contaminating microorganisms in samples. This testing should be applied to substances, preparations, or articles which, according to the Pharmacopoeia, are required to be sterile.

Charles River provides sterility testing through our Celsis® ATP-bioluminescence technology that is compliant with the requirements of the USP, EP, and current FDA regulations. Sterility testing is conducted by direct inoculation or membrane filtration methods and can be performed in an isolator or cleanroom environment. In conjunction with the sterility test, a bacteriostasis/fungistasis test is performed to assess whether the test article is inhibitory to the growth of microorganisms.

Microbial Limits Testing

Microbial limits testing is performed on pharmaceutical products and medical devices in order to monitor the levels of microbial organisms present during processing and handling. The information provided by this test can be used to help determine the sterilization dose for the product or device. This assay is designed primarily to allow quantitative enumeration of bacteria and fungi that may grow under aerobic conditions. Our Celsis® rapid microbial method reduces the long incubation times necessary for a quantitative assay with a qualitative, ATP-based bioluminescence automated analysis, a proven, gold standard for product screening and rapid release.