

Microbiological testing

Microbiological testing is essential for pharmaceutical producers to ensure patient safety and meet strict regulations.

Contamination can compromise product integrity, delay batch release, or lead to costly recalls. Normec Synergy Health supports manufacturers with comprehensive microbiological testing for both sterile and non-sterile products, in line with EU GMP and pharmacopoeial standards.





Microbiological Analyses

We offer a wide range of microbiological testing services to ensure the highest quality standards. We are dedicated to providing reliable and efficient testing solutions tailored to your specific needs.

Sterility Testing Services

Ensuring the sterility of your pharmaceutical products is crucial. We perform sterility testing according to USP/EP and ISO 11737 standards to confirm the sterility of products post-sterilization or aseptic manufacture.

- ISO Class 5 Cleanroom Suites
- Custom Method Selection and Design
- Testing for various products (from drug product to large medical devices)

Endotoxins Testing Services

Our Bacterial Endotoxins Test (BET) is essential for batch release testing of pharmaceutical products and medical devices that will be in contact with body fluids.

- Kinetic Turbidimetric Method
- Gel Clot Method
- Chromogenic Kinetic Method with Recombinant Cascade Reagents (rCR)

Microbiological assay of antibiotics

We provide microbiological potency testing for antibiotics, such as the diffusion (Cylinder-Plate) method, measuring the antibiotic's ability to inhibit the growth of target organisms.

Antimicrobial Effectiveness Testing

For products with antimicrobial claims, like preservatives in pharmaceuticals, we conduct effectiveness testing.

Our services include:

- Routine Analyses and Test Codes: Demonstrating the effectiveness of the preservative system in the product.
- Testing According to USP <51>: Inoculating the product with specified microorganisms and comparing the results over a 28-day period.

Bioburden Testing Services

Bioburden testing measures microbial contamination levels on or in products, ensuring compliance with microbial quality and sterilization requirements.

- Tailored Bioburden Testing
- Controlled Testing Documentation
- Speciation in Bioburden Testing

Microbial Limits Testing Services

Microbial limits testing ensures products meet established specifications for microbial quality.

Our services include:

- Routine Analysis and Test Codes
- Testing According to EP 5.1.4 or USP <61> and USP <62>
- Preparatory Testing

Get in touch today to learn how we can help ensure the sterility and quality of your pharmaceutical products.