



Microbiology testing

Health Inspired,
Quality Driven.

SGS

SGS

Protecting your patients, your reputation and your compliance

Microbiological risk assessment and characterization of pharmaceutical ingredients, including packaging, in bio/pharmaceuticals and medical devices are essential elements in the drug development process. Such practices ensure patient safety, product quality and longevity, compliance with regulations and reduces risk to your organization.

Pharmaceutical manufacturers are expected to characterize the microbial component of their drug products, excipients, packaging and all contact surfaces through production, handling and distribution processes to control or eliminate chances of contamination.

Whatever drives your need for microbiology and sterility testing, we can help you meet regulatory requirements and protect patient safety, efficiently and accurately.



A global network of 10 laboratories supporting your microbiology testing for pharmaceutical and biopharmaceutical products.

Our areas of expertise

Our microbiology testing experts provide a wide range of testing services, which support bio/pharmaceutical manufacturers at every stage of product development from discovery through to commercial release.

Antibacterial potency testing

Antibacterial potency testing measures the concentration of antibacterial active ingredients and is required for many products before they are released on the market. Our antibacterial potency testing is conducted using zone-of-inhibition or turbidity assessment against reference materials.

Antimicrobial effectiveness and microbial challenge testing

Our testing capabilities cover a wide range of scenarios, including microbial challenge testing for micro-organisms, and antimicrobial effectiveness testing for products in both sterile and non-sterile multi-dose forms.

Microbiological attribute studies

We offer a wide range of microbiological attribute studies, such as barrier testing for packaging, medical gloves or hygienic and antibacterial testing for contact lenses and personal care products.

Sterility testing

We conduct rigorous sterility testing under aseptic conditions in accordance with the European Pharmacopoeia 2.6.1 and USP <71> for pharmaceuticals and CFR 610.12 for biologics.

Other tests

We also support a wide range of other microbiology tests, namely:

- Bacterial endotoxins testing
- Chemical disinfectant testing and cleaning efficacy and cleaning validation studies
- Container closure integrity, including microbial ingress testing
- Environmental monitoring – of air and water in facility and manufacturing suites plus operator hygiene testing
- Facility qualification and validation to ensure adequate design and hygienic operating processes are effective to ensure cleanliness.
- Microbiological assessment of antibiotics
- Microbial isolation and identification (Vitek, API strips, Microseq, MaldiTof)
- Microbial limits tests (microbiological examination of non-sterile products) according to USP <61>/USP <62>
- Mycoplasma testing through both culture and PCR testing
- Non-viable particulate testing
- Preservative efficacy testing
- Sampling and analysis of water for pharmaceutical manufacturing

Our laboratories can organize the sample collection from the clients' manufacturing sites.



Trusted confidence from a world leader in testing services

Our microbiologists have a wealth of technical knowledge and experience. This includes the expertise required to develop and apply USP, Ph. Eur. and other international procedures, as well as client owned methods to a wide variety of biologics, traditional pharmaceuticals and medical devices.

As a world-leading provider of testing services and a leader in services for the health science sector, our global network of GMP laboratories meet the demanding cleanliness and engineering requirements for microbiological testing programs. We have Class 100 hoods, clean rooms and isolators available for microbial evaluation.

From development through to product launch and post-market support, the SGS team are here to assist you both at a local and global level with 27 sites located in 11 countries. Working with SGS ensures your product quality and safety every step of the way.



SGS can help you meet regulatory requirements and protect patient safety.

Health Science

Health Inspired,
Quality Driven.

Contact us

- ✉ healthscience@sgs.com
- 🌐 sgs.com/healthscience
- 🌐 sgs.com/healthcommunity

SGS

When you need to be sure