Microbiology

Discover our expert portfolio of microbiological analytical solutions
Unparalleled expertise in microbiology

Solvias offers a comprehensive portfolio of microbiological analytical solutions for sterile and non-sterile products backed by over 20 years of experience. Our ‘one-stop-shop’ approach includes tests for a full spectrum of pharmaceutical products, both small and large molecules, from raw materials and active pharmaceutical ingredients (API) to intermediates and commercial products, as well as medical devices. We also provide testing facilities most adapted to the testing of toxic compounds and environmental monitoring samples.

Our dedicated team of trained microbiologists is based at Confarma, the Solvias Group’s specialized site for biological analyses in Hombourg, France. Here, our state-of-the-art microbiology laboratories are equipped to offer a full range of testing techniques according to compendial methods as well as the flexibility to offer alternative rapid methods. We support you with quality control (QC) release testing of your products with appropriate laminar flows to ensure an aseptic environment, and provide method suitability testing, transfer and validation of client-specific methods.

Key competitive advantages

Customers appreciate our comprehensive and solution-oriented approach across all fields of the Microbiology. Our teams help you to solve any topic related to Microbiology.

In order to support you with the most advanced technologies, our rapid microbiological methods (RMM) enable our labs to deliver your results faster, for example with our rapid sterility test in just five days. We also offer the flexibility of training at customers’ own sites for specific techniques. Our research and development (R&D) department is able to provide development and validation of client-specific methods as well as alternative methods. In addition to Microbiology labs, our dedicated laboratories for molecular and cell biology enable implementation of methods using several techniques, all on one site.

We offer services according to GMP, cGMP, GLP, ISO 17025 (scope under www.cofrac.fr), OHSAS 18001, ISO 9001 and ISO 14001 standards.

A key competitive advantage of working with Solvias is the scale and scope of our services both on-site at Confarma and within close proximity across our other hub sites just across the border in the Basel area.

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**MICROBIOLOGY**

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**PYROGENICITY**

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- Final form: sterile
- Final form: non-sterile
Sterile products

Sterility testing is the most critical parameter for the release of sterile products. Besides sterility testing further tests are needed such as pyrogenicity, mycoplasma and CCIT.

Confarma’s international reputation for excellence in sterility testing includes our rapid sterility test, a technical innovation that is three times faster than traditional methods but also meets both regulatory and technical criteria. In order to ensure the most secure environment for your product testing, all sterility tests are conducted in an isolator (closed system). Our team of trained microbiologists brings extensive expertise in handling complex products such as antibiotics, gels, ointments, advanced therapy medicinal products (ATMPs) and medical devices.

- Sterility test according to compendial method Ph. Eur. 2.6.1. and USP <71>
- Rapid Sterility Test (RST): alternative method according to Ph. Eur. 5.1.6. and USP <1223>
- Bioburden: analysis of TAMC, TYMC and TAnaerobicMC according to Ph. Eur. 2.6.12. and USP <61>
- Media Fill Test (MFT) according to annex 1 GMP or FDA Guidance
- D-value determination of biological indicators acc. to ISO 11138 and USP <55> (BIER vessel)
- Verification of biological indicators (enumeration and identification) according to USP <55>
- Mycoplasma detection by qPCR acc. to Ph. Eur. NAT chapter 2.6.7.
- Container Closure Integrity Test (CCIT) by Microbial Ingress Test and Dye Ingress Test
- Mice Minute Virus (MMV) detection by qPCR
- Residual DNA detection by qPCR (eucaryotic cells such as CHO and HEK cells)
Non-sterile products

The presence of microorganisms in non-sterile preparations can reduce therapeutic activity and constitute a potential danger to patient health.

To help customers ensure compliance with GMP regulations and Pharmacopeias, our experts are experienced in conducting microbial enumeration test. Identification of microorganisms can be done readily when further investigation is needed. In our expert team we conduct specific assays such as microbial assay of antibiotics, with both Ph. Eur. 2.7.2. and USP <81> methods in place; and with experience with complex products such as ointments, liposomes and mixed antibiotics.

- Microbial Enumeration Test (MET) according to Ph. Eur. 2.6.12. / Ph. Eur. 2.6.13. and USP <61> / USP <62>.
  - Analysis of total counts TAMC, TYMC, TAnaerobicMC
  - Analysis of specific microorganisms such as E. coli, S. aureus, P. aeruginosa etc.
- Identification of microorganisms by DNA Sequencing and Maldi-ToF
- Preservative Efficacy Testing or Challenge Test acc. to Ph. Eur. 5.1.3. and USP <51>
- Microbial assay of Antibiotics according to Ph. Eur. 2.7.2. and USP <81>
- Growth Promotion Test of growth media according to Ph. Eur. 2.6.12.
- Water Activity determination (Aw) according to Ph. Eur. 2.9.39 and USP <1112>
Pyrogens and endotoxins

Pyrogen testing is essential to ensure the safety of pharmaceutical products with parenteral administration and for medical devices.

Solvias’ unique in vitro monocyte activation test (MAT) based on a human cell line MonoMac6 detects the full range of fever-inducing pyrogens including endotoxins. It offers a robust test system for QC release, in accordance with the EU legislative framework. Our teams are familiar with all formats of the MAT and have experience with product-specific method validation. In addition, we offer on-site consulting and training by our experts. With dedicated lab space for pyrogen testing, we offer broad experience with complex products such as vaccines, APIs, gels and medical devices. In addition, all compendial methods for Bacterial Endotoxin Test (BET) are in place in our lab.

- MAT in vitro pyrogen test according to Ph. Eur. 2.6.30.
  - Cell-line MonoMac 6: robust test system for QC release
  - PBMCs
  - Whole blood assay
- Bacterial Endotoxin Test (BET) or LAL Test according to compendial methods Ph. Eur. 2.6.14., USP <85> and JP 4.01
  - Kinetic turbidimetric assay (KTA)
  - Kinetic chromogenic assay (KCA)
  - Gel clot assay (GCA)
- Alternative method: Factor C
- Beta D glucan test
- Sample holding time and Low Endotoxin Recovery (LER) studies
Manufacturing environments need to be monitored from a microbial perspective so control of contamination can be demonstrated, reducing the both the risk to products and possible sterilization failures.

We bring extensive experience to support the monitoring of your production environment, including on-site sampling by our trained operators. With comprehensive and reliable techniques and knowledge in place, our customers benefit from full reporting and detailed interpretation of data along with on-site training and consulting services. We complement this offer with the design and implementation of specific studies to determine, for example, efficacy of your disinfectants.

- Identification of microorganisms by DNA sequencing and Maldi-ToF
- Mapping studies, qualification and monitoring of facilities
  - Risk-Based qualification protocol
  - Environmental qualification and monitoring
  - At rest and in operation qualification activities
- Clean utilities qualification and monitoring:
  - Water systems: microbiology, endotoxins and physico-chemistry
  - Clean steam: endotoxins
  - Pharmaceutical gases and process air: microbiology and particles
- On-site sampling
- Disinfectant efficacy studies according to USP <1072>, ISO 13697, ISO 1040 and 1275
  - Efficacy studies in suspension
  - Efficacy studies on surfaces
- Identification and cryo-conservation of client in-house strains