

PHARMACEUTICAL SERVICES

SWITZERLAND ANALYTICAL LABORATORY

Pharmaceutical & Medical Device Testing
Laboratory Services

Our Analytical Testing Expertise

Intertek's Switzerland testing laboratory, located in Reinach, near Basel, is an advanced analytical testing facility providing comprehensive pharmaceutical testing, materials analysis, and chemical testing to clients in the pharmaceutical, medical device, drug delivery, chemical, packaging, polymers, and consumer healthcare sectors across Europe and the world.



Our analytical testing laboratory provides advanced GLP/ GMP-compliant testing for various industries worldwide. We support clients throughout their product life cycle with state-of-the-art equipment and expert scientists.

Cutting-Edge Analytical Testing in the Heart of Switzerland

Our 2200m² Swiss testing laboratory in Reinach is equipped with state-of-the-art instrumentation, capable of performing chemical trace analysis, reverse engineering, complex analyses, substance identification and a wide range of other applications. With a significant corporate research heritage, the Intertek Reinach testing laboratory is staffed by highly trained and experienced scientists with many years of industry knowledge.

Our flexible approach includes project and study-oriented work to support customers at various stages of their product life cycle – from research and development, and registration, to ongoing production or post-market failure or complaints. We also provide a range of routine testing services to meet our client's current needs.

Your GLP/GMP Compliant Laboratory Services Partner

The laboratory provides analytical testing to Good Laboratory Practice (GLP) compliant requirements and is on the WHO list of Prequalified Quality Control Laboratories (since 2014). The laboratory has ISO 17025 certification for specific methods and ISO 9001 certification and holds Good Manufacturing Practice Compliant (GMP) certification and is FDA inspected.

Research and Development Analytical Laboratory Heritage

Our Reinach laboratory joined the Intertek network in 2010 after acquisition from CIBA Expert Services. We have a rich heritage of supporting some of the world's most innovative and largest companies, including Ciba Specialty Chemicals, Novartis, and BASF, as an in-house analytical testing laboratory supporting research and development and production. Since the acquisition, our laboratory has continually invested in our people and technologies.



LABORATORY SERVICES

- Extractables and leachables
- Method development and validation
- Pharmaceutical analytical support
- Impurities analysis/genotoxic impurities
- Particles and foreign matter investigation
- Counterfeit and falsified medicine investigations
- ICH stability services
- Polymer analysis and testing solutions
- Material technology expertise
- Medical device chemical characterisation
- Quality control testing

Pharmaceutical Testing Services



Extractables and Leachables

Our experts have over 30 years of experience in specialised analytical assessment for extractable and leachable testing covering primary and secondary container closure systems (CCS), single-use systems used in bioprocessing or vaccine production and ISO 10993-part 18 for medical devices. We also provide formulation/CCS interaction studies or compatibility testing and glass delamination studies.

Particles and Foreign Matter Investigation

Adopting a strategic approach to identifying contaminants, our team has expertise in sampling and sample preparation, visual/physical examination, chemical identification and root cause analysis. We deliver scientific, evidence-based insight to help you mitigate the impact of particulate contamination on product quality (and safety) or production efficiency.

Method Development and Validation

Across a wide range of analytical technologies, including chromatography, mass spectrometry, and spectroscopy, our scientists provide expert support for your analytical method lifecycle. From method development, improvement, qualification, validation, and method transfer to and from client laboratories, we support you across the various clinical stages to commercialisation and beyond.

Pharmaceutical Analytical Support

Our contract analysis services are focused on supporting product development, GMP manufacturing and distribution, from an early phase of development through to manufacturing and post-marketing analytical support. We provide method development and validation, stability testing, release testing (QC), extractable and leachables, genotox impurities analysis and cleaning validation and cleanliness analytical support.

Counterfeit and Falsified Medicine Investigations

We provide falsified medicine and counterfeit medicines analysis using investigative technology such as mass spectrometry (MS), infra-red (FTIR), RAMAN and nuclear magnetic resonance (NMR) spectroscopy, gas chromatography (GC-MS) and liquid chromatography - mass spectrometry (LC-MS) in the identification of fake medicines from our WHO accredited prequalified quality control laboratory.

cGMP Pharmaceutical Quality Control Testing

Our expert team offers GMP pharmaceutical quality control (QC) testing programs for raw materials, APIs, and intermediates to pharmacopeia specifications. We provide troubleshooting and specialist QC methods to ensure the highest standards.

ICH Stability Services

Our stability teams manage Good Manufacturing Practice (cGMP) stability studies, including ICH storage and accelerated studies for active pharmaceutical ingredients, finished pharmaceutical products, drug/device combination products, medical devices and consumer healthcare.

Genotoxic and Mutagenic Impurities Analysis

Our expert services include genotoxic impurities analysis to assess and control DNA-reactive mutagenic impurities in pharmaceuticals. The GMP labs support the identification, quantification, and control of genotoxic impurities in APIs and drug products.



- Good Laboratory Practice (GLP) compliant
- WHO list of Prequalified Quality Control Laboratories (since 2014)
- ISO 17025 and ISO 9001 certification
- Good Manufacturing Practice (GMP) compliant certification
- FDA inspected

Extractables & Leachables Testing

Extractables and leachables to quantify risks associated with leachable impurities from container closure systems for human drug packaging, food contact materials, process equipment, and medical devices.

Decades of Experience in E&L Analysis

Our experts have over 30 years of experience in specialised analytical and toxicology assessment for extractables and leachables testing from our GMP-compliant Swiss laboratory. Our E&L expertise, compliance, and regulatory work are reinforced by our knowledge of polymer, plastic, food contact, medical devices, and packaging materials, allowing us to identify components from the most complex polymer formulations, including adhesives, additives, stabilizer ingredients, and their degradation products.

Our consultants provide first-class evaluation and assessment of existing E&L data gaps. We offer the right study for your product through strategic screening or quantitative analyses, including chemical characterisation and identifying impurities.

Evolving Regulatory Expectations for E&L Testing

Regulatory agency expectations for extractables and leachables testing are continually evolving, with increasingly stringent requirements for evaluating product packaging associated with each new product.

Our scientists conduct E&L analysis studies in accordance with regional guidance and nationally and internationally recognised standards, including Good Manufacturing Practice (GMP), Product Quality Research Institute (PQRI) extractables and leachables guidelines, United States Pharmacopeia (USP) requirements (e.g., USP chapters <665>, <1665>, <1663>, <1664>, and <1664.1>), European Medicines Agency (EMA) guidance, US Food and Drug Administration (FDA) guidance, BioPhorum/BPOG guidance, and ISO 10993-18 extractables and leachables guidelines (Part 18). We also provide testing of glass packaging according to USP <1660> Glass Delamination Studies.



Medical Devices Materials Testing

Chemical characterisation of medical device materials, and biocompatibility testing for medical devices, supporting identification and control of biological hazards from material constituents.

Chemical Characterisation and Biocompatibility

Our laboratory experts specialise in designing comprehensive studies and delivering robust data for the chemical characterisation of medical device materials. We also offer biocompatibility testing for medical devices, including extractables and leachables, to support the identification and control of biological hazards from material constituents.

Our expertise includes:

- Method development and validation
- ISO 10993-18 chemical characterisation
- Toxicological risk assessment
- Chemical characterisation to ISO 18562 supporting biocompatibility evaluation of breathing gas pathways in healthcare applications
- Measurement of extractable and leachable materials from medical devices
- In-use simulation studies
- Assessment of processing residuals
- Batch-to-batch verification of materials
- Support for new material or new supplier evaluation
- Particulate testing and analysis and particulate release studies
- USP plastics and container testing
- Stability and ageing studies with controlled ICH storage conditions
- Verification of process changes to support production



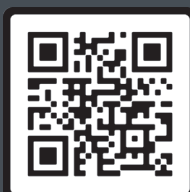


3D DIGITAL LABORATORY TOUR


Explore Our Cutting-Edge Analytical Swiss Laboratory with an Immersive 3D Tour


Join us for a virtual lab tour at Intertek's state-of-the-art analytical laboratory in Reinach, Switzerland. Our immersive 3D experience offers a fully interactive 360° digital tour, allowing you to explore our facilities from the comfort of your screen.

For more information and to request access, scan the QR code.





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