

Confidence[®] Extractables & Leachables Testing Services

Every polymer-based and elastomer-based component comes into contact with a drug substance or drug product, biopharma manufacturers need to assess whether an interaction has occurred. You need to make that determination based on scientific evidence, all while navigating increasingly complex single-use architectures, ever-tightening analytical expectations, and a regulatory landscape now anchored by USP <665>, <1665>, <1663>, and <1664>.

Sartorius brings together decades of experience in materials science, state-of-the-art analytical chemistry, and a dedicated team of specialists in extractables and leachables (E&L) to give you exactly that: a defensible, science-based answer that's tailored to your process and your product — delivered by an organization that manufactures many of the components you're qualifying. We offer manufacturers a collaboration that provides depth of knowledge and a faster, more confident path from development to regulatory submission.



Innovative, simulation-driven extractables assessments

Beyond conventional testing, our extractables assessments — facilitated by our proprietary extractables simulator software, ExSim — enable us to model and scale extractables profiles across component combinations, even if they've never been physically tested together. This is particularly valuable for complex, multi-component single-use assemblies, where testing every possible permutation on the bench would be impractical and redundant. ExSim gives you a scientifically robust profile without the added cost and lead time of exhaustive physical testing.

Analytical depth aligned to USP <1663> and <1664>

As specified in USP <1663>, USP <1664>, and sub-chapters, we deploy a comprehensive suite of orthogonal, state-of-the-art analytical techniques to detect, quantify, and identify compounds released from polymer-based materials—including within the most complex product formulations. Our analytical toolkit includes:

- GC-MS: Volatile & semi-volatile organic compounds
- HPLC-UV: Non-volatile organic compounds
- LC-MS: Volatile organic compounds and polar extractables
- HS/GC-MS: Headspace volatile organic compounds
- ICP-MS/OES: Elemental impurities

Crucially, we don't treat these outputs as isolated data points. We combine extractables, material, plastics, and toxicological data with intelligent algorithms to perform process-specific extractables and leachables scaling—even for multi-component assemblies—to turn raw analytical results into a risk-relevant, decision-ready picture of your specific manufacturing process.

Regulatory expectations for single-use systems

USP <665>, "Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products," together with the informational chapter USP <1665>, establishes a structured, risk-based framework for evaluating every polymeric component in a single-use manufacturing train. Rather than treating extractables testing as a one-time checkbox, the chapters call for a two-step approach: an initial assessment to determine whether a given plastic component requires testing, followed by a formal risk assessment for the specific application, informed by the degree and duration of contact between the component and the process stream.

Components are subsequently categorized as low, moderate, or high risk, and that categorization drives the scope and depth of the required extractable and leachables profiling. The intent is to identify process equipment-related leachables (PERLs) before they can accumulate across a manufacturing train and compromise product quality, stability, or patient safety—and to ensure that data generated under long-standing industry frameworks, including BioPhorum/BPOG protocols, aligns with the new USP expectations, and isn't assumed to be equivalent.

Why biopharma manufacturers choose Sartorius for E&L testing



Proprietary scaling technology

Our proprietary ExSim software scales extractables data intelligently across complex, multi-component assemblies without redundant physical testing for every configuration.



Built for compliance

Our testing is designed and executed in strict accordance with USP <1663>, <1664>, <665>, and <1665>, so your data package withstands regulatory scrutiny the first time.



Proven at scale

Our dedicated team of study directors has completed more than 6,000 E&L projects for customers around the world.

Regulatory expectations for container closure systems

For container closure systems, the governing framework rests on USP <1663>, “Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems,” and USP <1664>, “Assessment of Leachables Associated with Pharmaceutical Packaging/Delivery Systems,” building on the FDA’s foundational 1999 guidance on container closure systems for packaging human drugs and biologics.

Because container closure system design is typically fixed and application-specific, regulators expect a correspondingly rigorous and well-defined qualification scope: extractables studies conducted under deliberately exaggerated conditions to generate a comprehensive migrant profile, followed by leachables studies performed in real or simulated conditions to confirm which migrants are actually relevant to patient exposure. Manufacturers must report any newly identified leachable and, where necessary, perform a toxicological evaluation. As global harmonization efforts continue—including planned enhancements to USP <1663> and <1664> and new dosage form-specific chapters—manufacturers should expect the bar for reproducibility and non-targeted screening confidence to keep rising.

Sartorius ExSim software

Complex single-use assemblies routinely combine multiple bags, tubing sets, filters, and connectors into configurations that are unique to your process. Testing every possible combination physically is rarely feasible within realistic project timelines. Our proprietary ExSim simulation software gives you a scientifically sound, assembly-specific extractables profile without the burden of exhaustive physical testing:

- Flexible scaling: Precisely scale extractables data, even for complex, multi-component assemblies.
- Comprehensive extractables profile: Identify all chemically relevant entities present and build a complete and defensible migrant profile for your process.
- Extractables assessment: Compile all findings into a tailored risk assessment to build a decision-ready regulatory narrative.

A state-of-the-art laboratory, backed by proven expertise

Our E&L testing operations are located in a dedicated laboratory in Göttingen, Germany, purpose-built to maximize flexibility across test methods. Rather than routing every sample through a fixed, one-size-fits-all workflow, our facility is equipped and staffed to adapt method design to the circumstances of your specific formulation, material set, and manufacturing process.

The capabilities of our laboratory are equally matched by the people working inside. Our team of E&L experts includes experienced study directors embedded directly within the project team, as opposed to a separate layer of sign-off that only occurs at the end of the process. That means the people designing your extraction protocol, interpreting your chromatograms, and building your risk assessment understand your regulatory timeline and your product’s constraints from day one.

Talk to our E&L specialists about your single-use system or container closure qualification needs and discover how ExSim can accelerate your SUS risk assessment.

Get in touch with our E&L specialists via our e-shop:

[Extractables & Leachables Testing](#) | [Validation Services](#) | [Sartorius eShop](#)



Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

USA

Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

 For further contacts, visit
[sartorius.com](https://www.sartorius.com)