eurofins | BioPharma Product Testing

From Compliance to Confidence: Master USP <665> with Expert Support

USP <665> and <1665> require rigorous extractables and leachables (E&L) testing for all single-use systems (SUS) - including tubing, filters, containers, and connectors.

With USP <665> enforcement beginning May 1, 2026, pharmaceutical and biopharmaceutical manufacturers must meet strict new standards for plastic components used in drug production.

Non-compliance isn't just a risk, it's a liability, leading to regulatory delays, product recalls, compromised patient safety. As the deadline approaches, you need analytical and regulatory experts already engineering solutions for what's next.

Your Compliance Partner: From Testing to Strategy

We don't just help you meet the standard - we help you lead with confidence and future-proof your products to avoid costly delays or rejections.

Our labs are powered by cutting-edge analytical technology and led by industry-recognised experts in E&L science, offering proactive guidance, risk mitigation strategies, and clear, collaborative communication every step of the way.

We bring unmatched knowledge of polymers, plastics, adhesives, and packaging materials, enabling us to identify even the most complex extractables and degradation products.

Our experts have delivered high-impact analytical and toxicological solutions across a wide range of complex products.

Whether you're launching a new product or qualifying new materials, we deliver science-driven, regulatory-ready insights that help you move forward, faster and safer.

Our Services

Extractables & Leachables testing

Ensure your single-use systems (SUS) meet the stringent requirements of USP <665>, <1665>, and BPOG protocols:

- Controlled extraction studies using aggressive solvents and conditions.
- Targeted and untargeted screening for organic and inorganic extractables.
- Simulation of real-use conditions to identify potential leachables.
- Quantitative risk assessment of detected compounds.

Analytical method development & validation

We tailor analytical methods to your materials and regulatory needs:

- Development of custom LC-MS, GC-MS, ICP-MS methods.
- Validation per ICH Q2(R2) guidelines.
- Robust detection of trace-level impurities and unknowns.

Characterisation of unknowns

Identify and assess unknown extractables with:

- High-resolution mass spectrometry (HRMS).
- Structural elucidation using NMR and FTIR.
- Toxicological risk assessment of unknowns.

Toxicological services

Our in-house toxicologists provide:

- Strategic gap analysis of your current E&L data.
- Tailored study designs that align with your product and regulatory goals.
- Robust safety assessments to support confident regulatory submissions.

Regulatory strategy & submission support thanks to the dedicated Eurofins BPT Consulting Europe division:

- Gap analysis of current data vs. USP <665> requirements.
- Preparation of regulatory documentation for FDA, EMA, and other agencies.

Risk assessment & mitigation

Implement a science-based approach to risk:

- Material risk profiling using USP <1665> and BPOG matrices.
- Leachables risk modeling based on dosage and exposure.
- Recommendations for material changes or supplier qualification.

Contact Us

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