

Non-destructive CCI
testing for parenteral
packaging having
elastomeric closures



USP <382> Compliant CCI Testing



A New Standard Requirement for Container Closure Integrity Testing (CCIT)

With USP <382> now an official requirement, manufacturers must demonstrate the functional suitability and inherent integrity of fully assembled packaging systems that include elastomer components.

Traditional blue dye ingress methods are destructive, subjective, and not sensitive enough to meet modern regulatory expectations.

USP <382>, together with USP <1207>, calls for deterministic, quantitative methods capable of verifying Maximum Allowable Leakage Limits (MALL) under realistic conditions.

Helium leak detection and laser-based headspace analysis are the only two deterministic technologies capable of detecting leaks down to the submicron level. Among these, laser-based headspace analysis stands out for its ease of use, non-destructive nature, and its suitability as a CCIT solution across the entire product lifecycle.





Deterministic CCIT with Laser-Based Headspace Analysis

LIGHTHOUSE provides fully validated, non-destructive CCIT using laser-based headspace gas analysis. Combined with a CO₂ tracer gas challenge, our service delivers objective, quantitative evidence of package integrity and elastomer self-sealing performance down to the MALL.

Primary Applications

- Inherent Package Integrity Verification (USP <382> Section 4)
- Needle Self-Sealing Capacity (USP <382> Section 5.2)

Benefits

- **100% Deterministic & Objective**
Quantitative and analytical gas flow data.
- **Ease of Use and Completely Non-Destructive**
Measure CCI for all containers in one single batch within minutes
- **Regulatory Alignment**
Directly supports USP <382> and USP <1207> deterministic testing guidance
- **High Sensitivity**
Validated leak detection limits aligned with the strictest MALL requirements
- **Real-Time Self-Sealing Insight**
Capture elastomer resealing dynamics after needle withdrawal
- **Lifecycle Applicability**
A CCIT approach suitable for development, validation and commercial production



Proven Expertise You Can Trust

- More than 30 years of experience in laser-based headspace analysis
- Trusted by leading pharmaceutical manufacturers for USP <382> implementation
- Methodology aligned with USP <1207> deterministic CCIT expectations

Get in touch

Ready to transition to a holistic container closure integrity evaluation?

Email us at: CCITExperts@lighthouseinstruments.com
or visit: www.lighthouseinstruments.com