

Container Closure Integrity

Insights from the Experts

As new biologics are developed and storage conditions as well as packaging becomes more complex, it is even more important to understand the integrity of the package and the appropriate way to evaluate and test it.

West has an extensive portfolio of Container Closure Integrity (CCI) techniques and analysis for various packaging and delivery systems to meet the needs of pharmaceutical, biotech and medical device manufacturers. Through unmatched customer support, and the technical expertise to design and execute a variety of studies, partnering with the CCI experts at West offers the flexibility to maintain or explore packaging solutions that may increase a drug product's overall value and help ensure patient safety.

Our extensive portfolio of CCI techniques and analysis for various packaging and delivery systems are based on package type, product fill and storage condition. West's experts have the capability and technology to scientifically observe these aspects of packaging systems through the deterministic methods and areas of concern as outlined in USP <1207>. We guide our customers through the regulatory landscape from package development and selection, inherent CCI, establishing a maximum allowable leakage limit and life cycle management.

The West Analytical Services' facility offers the full battery of techniques and capabilities as described in USP <1207>, including:

- Tracer Gas Detection, vacuum mode (helium mass spectrometry)
- High Voltage Leak Detection
- Frequency Modulation Spectroscopy (oxygen headspace)
- Tracer Liquid (dye ingress)

In addition, West offers a wide variety of storage capabilities to fit a variety of needs for products and packages. We are able to perform CCI analysis at the below temperature conditions in real time, providing an accurate CCI assessment:

- Ambient
- Refrigerated
- Frozen
 - -20 C
 - -80 C
 - -120 C
 - Liquid Nitrogen

Using West Analytical Services' repertoire of rapid and nondestructive container closure analysis systems helps to maintain drug product efficiency, reduce time to market, increase quality and control costs.

Contact the **West Analytical Services** team today to design a program to meet your CCI testing requirements.
WestAnalyticalServices.com

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