



Laboratory
Services

CCIT Comparison

How Alcami Supports Your Quality Strategy

Alcami acts as a strategic partner by offering a comprehensive suite of CCIT services that span the entire drug product lifecycle—from early-phase development to commercial release and stability testing. By integrating both microbiological and analytical chemistry expertise, Alcami can help navigate complex regulatory requirements like USP <1207> and USP <382>. Support extends beyond simple testing; we provide tailored method development, validation, and specialized technical support for challenging formulations, including biologics and cell/gene therapies. With state-of-the-art laboratories and a focus on non-destructive deterministic methods, Alcami ensures that your container closure systems maintain their sterile barrier, ultimately mitigating supply chain risks, meeting regulatory expectations and safeguarding patient safety.

CCIT Methodology Comparison: A Technical Overview

The following overview provides a side-by-side comparison of Container Closure Integrity Testing (CCIT) techniques and capabilities. As the pharmaceutical industry moves toward more rigorous standards, understanding the distinctions between Deterministic and Probabilistic methods is essential for ensuring product sterility and patient safety.

The Deterministic Advantage

Deterministic methods, such as Vacuum Decay, Pressure Decay, CO₂ Headspace and O₂ Headspace Analysis, offer several critical advantages over traditional probabilistic methods like Microbial or Dye Ingress:

Quantitative Results:

These methods provide measurable data (e.g., pressure changes) rather than relying on qualitative visual observations.

Higher Sensitivity:

Deterministic tools can frequently detect defects as small as 10 µm whereas probabilistic methods often rely on experimental determination.

Speed of Analysis:

While a Microbial Ingress test requires weeks for organism growth, deterministic tests typically yield results in minutes.

Non-Destructive Nature:

Most deterministic methods (excluding QPLT) allow the sample to remain intact, whereas probabilistic methods are inherently destructive.

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	Method	Destructive?	Compendial Classification ²	Sensitivity	Works Best For	Test Time
Microbial Ingress	The container is immersed in a microbial suspension and placed in a pressure chamber. Growth of the organism in the sample solution indicates an active leak in the container.	Yes	Probabilistic	Experimentally determined	Media Filled Containers	Weeks
Dye Ingress	The container is immersed in a dye and placed in a pressure chamber. Detection of dye in the sample solution indicates an active leak in the container.	Yes	Probabilistic	1 µL of dye ingress (20 µm defect)	Rigid Container Closure Systems with no UV interference	Hours
Vacuum Decay	The container is placed in a monitored vacuum chamber. An increase in pressure during test time indicates a leaking headspace.	No	Deterministic	10 µm defect	Small Molecule DP Solutions with Gaseous Headspace	Minutes
Pressure Decay	The container is placed in a monitored pressure chamber. A decrease in pressure during test time indicates a leaking headspace.	No	Deterministic	10 µm defect	Large Molecule DP Solutions with Gaseous Headspace	Minutes
O ₂ Headspace Analysis	For containers blanketed under nitrogen, if oxygen is detected in the headspace, an ambient leak is indicated.	No	Deterministic	0.2 – 1% O ₂	Samples with Inert Headspace	Minutes
CO ₂ Ingress	The container is placed in a monitored pressure chamber overfilled with CO ₂ . Detection of CO ₂ in the sample headspace indicates an active leak in the container.	No	Deterministic	10 µm defect	Any DP Solutions with Visible Headspace	Minutes – Hours
QPLT ¹	Force is applied to the plunger of a sample syringe. Movement of the plunger or loss of mass is quantified to determine a leaking syringe.	Yes	Deterministic	10 – 20 µm defect	Pre-filled Syringes even with no Headspace	Minutes

¹ Quantitative Pressure Leak Test

² USP/NF <1207.2> has two CCIT classifications. Deterministic methods are preferred per USP/NF <1207.2> if possible.