

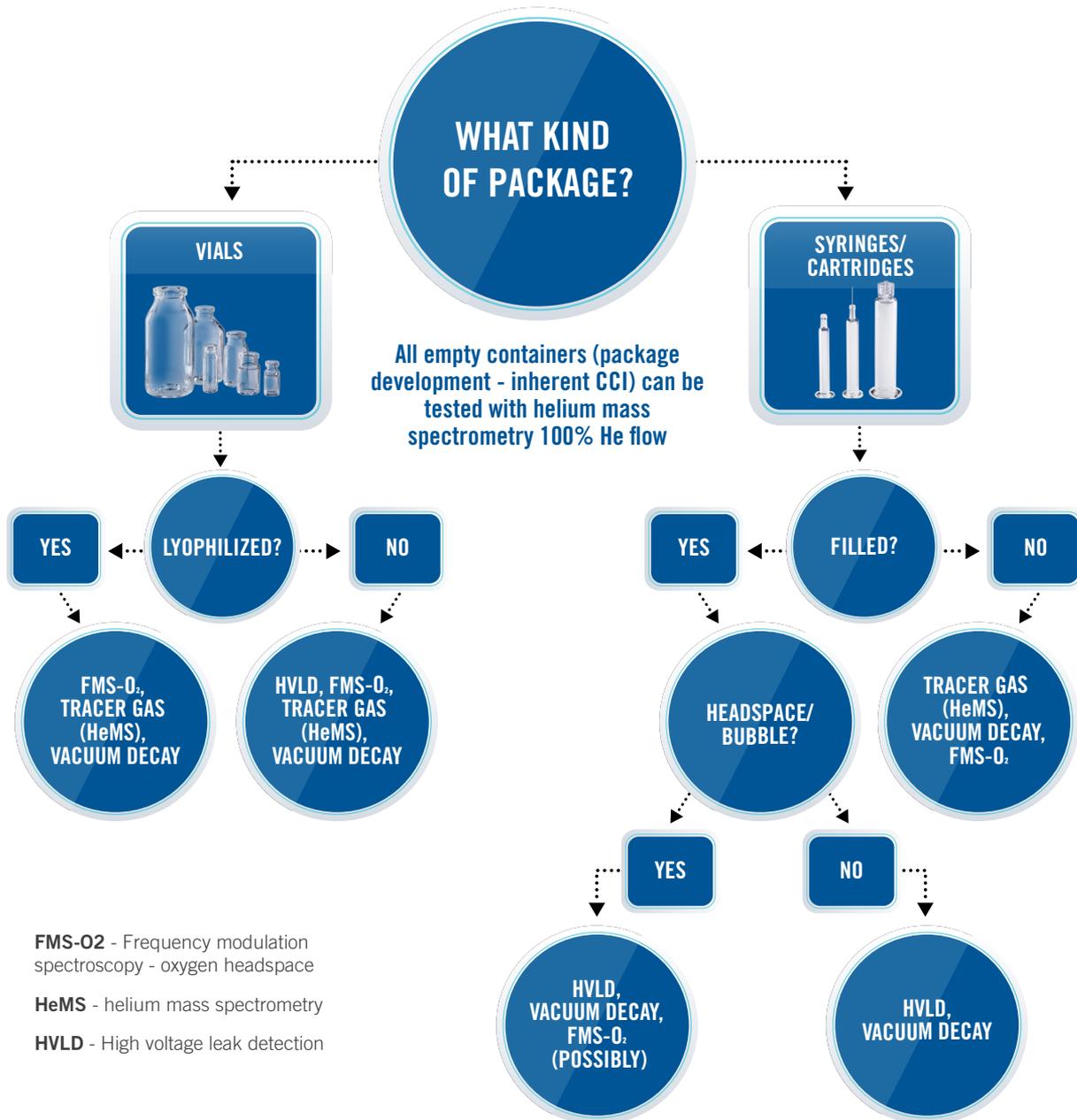
Analytical Laboratories Container Closure Integrity

West Analytical Services 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. Based on package type, product fill and storage condition, West's experts have the capability and technology to scientifically observe all of these aspects of packaging systems through the deterministic methods and areas of concern as outlined in USP <1207> (listed below). We are situated as a scientific destination to help guide our customers through the regulatory landscape from package development and selection, inherent CCI, establishing a maximum allowable leakage limit and life cycle management.

Technology	Helium Mass Spectrometry				High Voltage Leak Detection	Oxygen Headspace
Temperature Condition	Ambient	-80°C	-120°C	-180°C	Ambient	Ambient
Vials	Glass < 250 mL & 500 mL (empty)	Glass and CZ < 50 mL	Glass and CZ < 10 mL	Development Required Feasibility Required	Glass and CZ Fixture Dependent Feasibility Required	Glass and CZ Fixture Dependent 2 - 20 mL Feasibility Required
Syringes	Glass and CZ Empty luer lock 100% helium flow	Ambient Only	Ambient Only	Development Required Feasibility Required	Glass and CZ Fixture Dependent Feasibility Required	Glass and CZ Fixture Dependent 1 mL Feasibility Required

CCI Technology Decision Tree

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



For more information about West Analytical Services, contact your Account Manager today.

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