

# Helium Leak Testing: Pharmaceutical CCIT Methods and Applications

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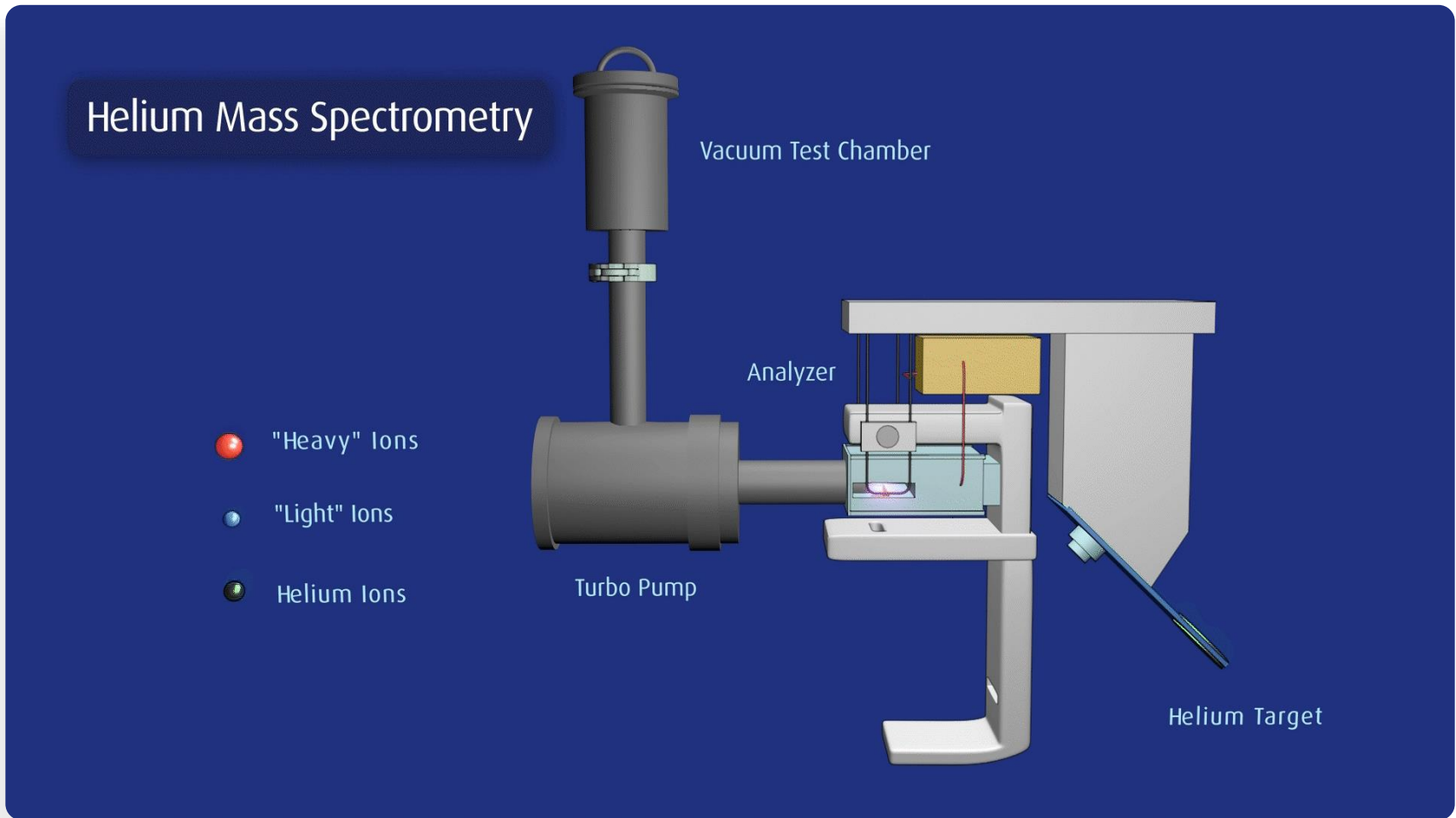
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# Helium Leak: What is it and How does it work?

- Gas molecules flow into an ionization chamber/analyzer cell.
- Filament electron beam ionizes molecules.
- Ions travel according to an acceleration voltage, and a magnetic field causes deflection relative to mass/charge.
- The analyzer cell is specifically tuned for the mass/charge of helium.
- Stream of helium ions hitting the target is reported as leak rate
- Mass Spectroscopy is a four-step process: ionize, accelerate, deflection, & detect
- The helium flow rate must be normalized to 100% helium

# He Leak Testing: Gas Flow Animation



# Package Formats & Applications Most Suitable for He Leak Testing

- Foil Blistercards & Foil Pouches/Sachets
- Glass Vials/Syringes/Cartridges
- Pharma Foil Tubes – Centrifuge Tube Containers
- Plastic Packaging – Ophthalmic Bottles, Vials, Syringes
- IV Bags – Sniffer Mode & Hard Vacuum Methods
- Medical Devices – Pacemakers, Injectors
- Industrial Applications – Weld Joints, Tube Connections, Valves, Pumps

# He Leak Testing: The 3 Principle Methods

## 1. *Hard Vacuum Method-Vacuum Chamber*

- Samples filled/flushed with helium, placed in vacuum chamber, chamber evacuated, and global helium leak rate obtained.
- Examples: Vials, Blistercards, pouches
- Need Helium concentration to normalize Helium Leak rate obtained from the vacuum chamber test.

## 2. *100% Helium Flow*

- Area of leak interest is placed under vacuum using custom designed fixtures.
- 100% helium gas flow is maintained on atmosphere pressure side of test fixture. Any increase over background leak rate is a breach or leak pathway
- Ex: Any Plastic container: vials, bottles, syringes, cartridges. Glass containers with pre-drilled hole for helium gas flow.
- No need for leak rate correction since 100% helium concentration is used during test.
- Fast, simple method. Most cycles < 30 seconds

## 3. *Sniffer Mode Method*

- Site specific probe used to scan for helium leakage in packages/objects containing helium gas.
- Ex: IV bag seals & port fittings, large vessels & tubing
- Not quantitative – pass/fail only – helium in atmosphere limits detection

# He Leak Testing: Hard Vacuum Apparatus



Rectangular Chambers  
Blistercards/Pouches



Cylindrical Chambers  
Vials

# He Leak Testing: 100% He Flow Apparatus



Plastic Vial Test Fixture



Plastic Vial Fixture  
(test ready)



Foil Tube - Closure  
Leak Test Fixture

# He Leak Testing: 100% He Flow Apparatus



Induction Seal  
Vacuum Fixture



Syringe Barrel  
Needle Fuse Leak Test Fixture



# He Leak Testing: 100% He Flow Apparatus



Glass Jar – Closure Fixture



Helium Flow Meter

- Device allows a measured flow of helium into a container for package for continuous 100% helium flow method testing.
- Flowmeter calibrated specific to Helium gas.

# He Leak Testing: Sniffer Mode



Foil Bag Sniff Leak Test

# He Leak Testing: Case Study - Blistercards

## Issue: Early-Stage Stability Failures



- Alu-Alu cold formed blisters exhibited product failures in accelerated ICH storage conditions. Wafer type product - very hydroscopic.
- Client performed Bubble & Dye ingress at time of packaging with passing results.

## Helium Leak Test to the Rescue!



- Blister samples were manually filled/flushed with helium gas. Adhesive backed Foil disks sealed puncture sites.
- Using the Hard Vacuum method, samples displayed high helium leak rates.
- These leak rates were below the LOD for bubble/dye testing, however they were at a level to allow premature water vapor entry in the cavities, thereby compromising the product.

# Cold Temp Helium Leak Testing



- Enables low temperature vial & syringe leak testing at temperatures from 0°C to ~ -150 °C
- Provides real-time sample temperature monitoring via TC connection; vacuum chamber attaches to inlet port of Helium Detector

# He Leak Testing: Validation Hardware



## External Helium Leak Standards

- NIST traceable Helium Leak standards are available in a wide range of helium leak rates
- Validates the detector response of the SIMS Helium Leak Testing systems up to the test port – point of sample testing.
- Direct connect to Leak Detector inlet port.



# Thank you

For additional information, please contact me: [j.morrow.lucas@ptiusa.com](mailto:j.morrow.lucas@ptiusa.com)

Or visit our site: <https://www.ptiusa.com/technologies/helium-leak-detection>

