

Helium Leak Testing: Case Study: Foil Tube Package

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CCIT Background & Challenges:

- Client: Major manufacturer of Ophthalmic products
- Container: Foil Tube package – dispensing nozzle/cap with crimp tube end. Nozzle is mechanically fused to the foil tube body
- Tube Package purchased from one primary vendor
- Client Leakage criteria: Must provide sterility barrier
- Helium Leak Rate (L/R) to assure sterile barrier: < 6.0 E-06 mbar-L/sec (Kirsch criteria)
- Modified L/R for added safety factor: 1.0 E-06 mbar-L/sec
- Tube manufacturer strictly using vacuum bubble test
- Client needed a more robust and sensitive leak test method
- Helium Leak test implemented to meet client requirements

Tube Package Application-He Leak



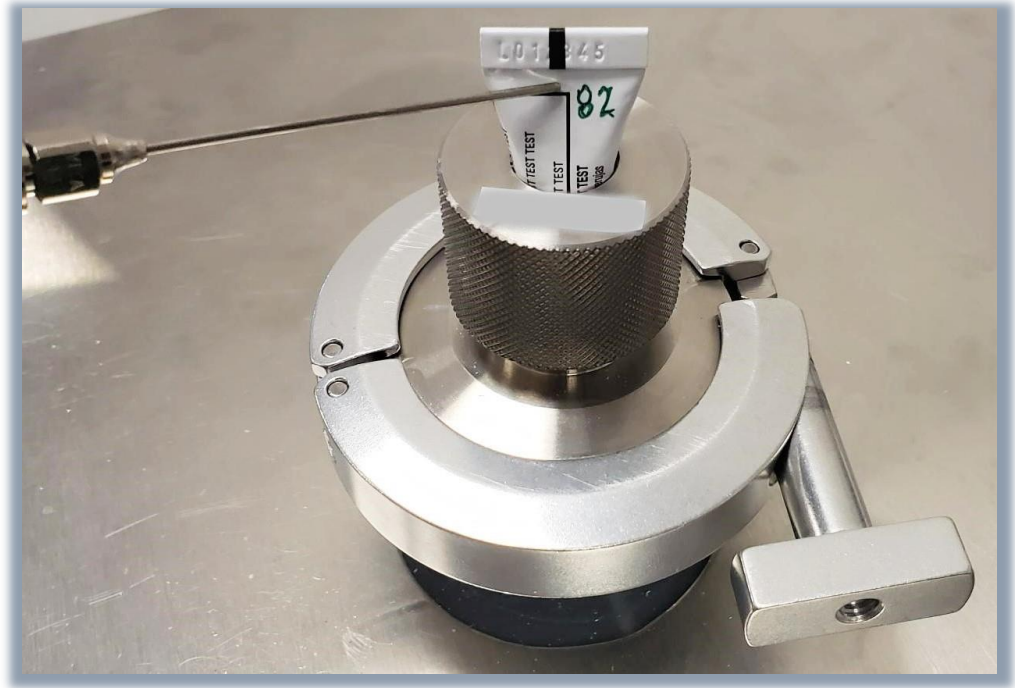
Representative Finished Package Samples

He Leak Testing Approach:

100% Helium Flow

- Area of leak interest is placed under vacuum using custom designed fixtures – Cap/nozzle and Crimp end.
- 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
- No need for leak rate correction since 100% helium concentration is used during test.
- Fast, simple method. Test cycles < 20 seconds

He Leak Testing Approach: 100% Flow



← Cap/Nozzle seal

↑ Crimp End seal

Tube He Leak Testing: Results

- Sample size: 100 tubes
- No helium leak failures on crimp end of tube (<2.0 E-09 mbar-L/sec)
- Twenty-three percent (23%) helium leak failure rate of the cap/nozzle end.
- Of the above failures, sixty-eight (68%) failed the Kirsch criteria helium leak rate (>6 E-06 mbar-L/sec).
- Slight modifications to the tube manufacturing process yielded similar helium leak test results.

Tube He Leak Testing: Results, cont.

- Tube manufacturer feared losing a major client since their tubes could not pass the helium leak test at a mandated 100% level.
- Client needed a suitable leak-tight package to ensure product safety.
- ***How could this to be rectified??***

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- Tube manufacturer performed a complete re-design of the foil tube mandrel used to form the nozzle/tube interface.
 - Additional helium leak testing confirmed this new tube forming process was successful in eliminating helium leak pathways.
 - Tube manufacturer will be adding a helium leak test system to their quality group to assure packages remain leak tight.

Key Case Study Take-Aways:

- Probabilistic leak test methods are simply not adequate in providing reliable, repeatable CCIT data. Tube packages passed the manufacturers bubble test yet showed a high level of failure when a deterministic method (Helium Leak) was employed.
- Had the previous leak test methods remained in place, product sterility issues would have no doubt arisen.
- Packaging suppliers may sometimes need to “think outside the box” in order to produce an acceptable package format for the client/end-user.
- Packaging Engineers and others that are tasked in providing acceptable packaging containers may also at times need re-evaluate their current CCI methods and technologies to ensure that their specific requirements are met with a high degree of confidence.

