Savillex
Your Fluoropolymer Solutions Partner

# Savillex Technical Note

## Integrity Testing of Purillex® Containers for Life Science Applications


## Summary

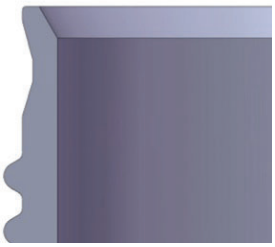
Container integrity testing is critical to ensuring leak-free operation of containers as well as protection of critical process solutions and final products. This testing is even more important when the process is an aseptic one. Container integrity can affect not only product sterility but also process yield, product stability, and several other critical attributes. Poor integrity can cause product adulteration and loss, leading to higher costs and process downtime.

Currently, there are several direct and indirect methods for testing container integrity. Direct methods include pressure decay testing, burst testing, and helium leak testing. Other methods can include dye-penetrant testing, bacterial ingress testing, and container sterility testing. However, these methods are often not as precise, open to interpretation, and can be prone to operator error.

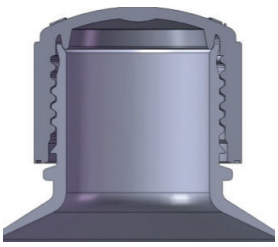

*Pressurized integrity testing of Purillex® containers*

Fluoropolymer bottles, vials, and jars are the ideal containers for applications requiring absolute integrity because of their unmatched durability, strong seal integrity, and imperviousness to a very wide range of temperatures. Purillex® containers from Savillex are designed with ferrule-style closure systems, which are unmatched in the life science industry.

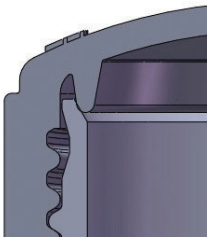
This technical note outlines three available methods to test Purillex PFA containers for container and closure system integrity in critical applications.



*Purillex® Bottle Neck – Lip Detail*



*Purillex® Bottle Neck Closure*



*Purillex® Bottle Closure – Detail*

## Test Method 1 – Hydrostatic Pressure Decay

Hydrostatic testing allows the detection of leaks that only become obvious at elevated operating pressures. The added benefit is that fluid may leak from the system and be visually detectable with a very small change in pressure – even at a pressure below those detectable by pneumatic test systems.

On the other hand, pneumatic tests are potentially more dangerous than hydrostatic tests because of the higher level of potential energy stored when compressing the gas. All Purillex containers are tested using the following hydrostatic pressure decay testing prior to lot release:

1. Drill and tap fitting into container closure system and attach a pressure supply line
2. Support water-filled container in an inverted position
3. Pressurize to 2 psi
4. After 5-minute period, observe threaded area using the backlight to observe for any water droplets
5. Pressurize to 15 psi
6. After 5-minute period, observe the threaded area using the backlight to check for any water droplets

Pass criteria: No water droplets observable in the threaded area of the container closure system

## Test Method 2 – Pressure at Failure

The pressure burst test is destructive and intended to measure the pressure at which an object will catastrophically fail or "burst." An object is attached to a test port and pressurized with regulated air during this test. Pressure sensors measure the pressure ramp rate and burst event, then compare them to predetermined limits for a pass or fail.

This test is holistic and can help to determine overall container durability quickly, detect material defects, and ensure elements like uniform material thickness are in control. Samples from each lot of Purillex PFA containers are tested for pressure at failure.

## Test Method 3 – Helium Leak

Helium leak testing is a method that quantitatively measures the associated leak rate for the test containers' closure integrity using helium mass spectrometry. Containers are prepared by torquing the closure to predetermined values using a calibrated torque wrench. The values applied are at or below the recommended closure torque values during use.

The leak test method is performed per USP <1207> Package Integrity Evaluation – Sterile Products and according to ASTM F2391-05 (2016) standard test method for measuring package and seal integrity using helium as the tracer. Both vacuum mode and pressure mode are used during the test.

A separate method feasibility study is often performed to confirm that the application of helium leak technology was fit for the assessment of the container closure system and to develop an appropriate technique for testing the container. Permeation trials are conducted to help differentiate between helium permeation through component materials and actual leakage.

Helium leak testing is performed on Purillex containers by customer request. This testing is often performed on containers used in extremely critical applications like master cell banking and long-term storage of process archive samples.

## Conclusion

Container integrity testing is crucial to ensure container integrity and protection of critical solutions. The three testing methods outlined in this technical note are routinely performed on Purillex PFA containers to ensure consistency, reliability, and product security during use.



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