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Savillex Technical Note

ASTM D4991 Testing for Purillex® Containers

Summary

Many customers in the fields of tissue engineering and cell therapy come to Savillex when their standard, off-the-shelf labware fails during shipment. Failures are most common after air shipments and are evidenced by liquid leaks detected upon receipt. A live tissue or cell sample being shipped to a hospital or clinic as part of treatment can be a catastrophic failure that can lead to damaged samples, surgical delays, and poor patient outcomes. Therefore, those selecting containers for critical CGT applications should pay attention to containers tested to ASTM shipping test standards.

The ASTM D4991-07(2015) Standard Test Method for Leakage Testing of Empty Rigid Containers by Vacuum Method is a standard test method that covers the testing of empty rigid containers under differential pressure conditions like those which can occur during air transport. It is an essential test for those considering using bottles, jars, vials, or other containers for critical shipping applications, particularly when maintaining sterility is required. However, the test is difficult for standard containers to pass and is often necessary for the most vital applications like hazardous liquid shipment. This Technical Note describes the testing of Purillex® bottles and jars at an independent lab to meet the requirements of ASTM D4991.

Purillex® PFA Bottles and Jars

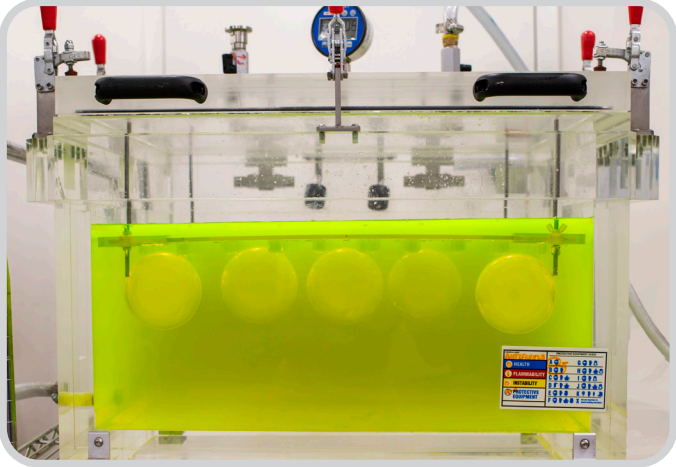
ASTM D4991-07(2015) Test Method

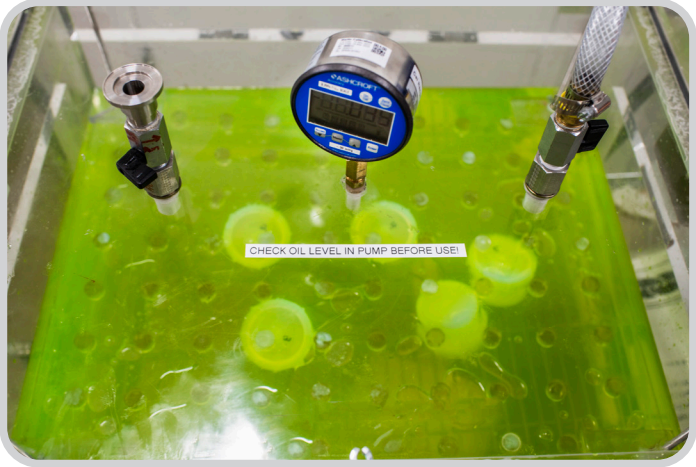
Empty rigid containers are prepared by sealing the closures using the operational torque setting, which simulates actual usage and the same torque used during Container Closure Integrity Testing (CCIT). The containers are then immersed in an ethylene glycol-water solution in a sealed, transparent test chamber. The chamber is then subjected to a gradually increasing partial vacuum. During de-pressurization, the containers are observed for signs of leakage in the form of air bubbles leaking from the closure seal. Once testing is complete, each container is also inspected for the presence of fluid in the container. Passing containers show no signs of bubbles during de-pressurization and no signs of fluid leaking into the container.

Purillex® PFA Bottles and Jars Pass ASTM D4991 Testing

Five (5) 1000 mL Purillex PFA bottles and five (5) 120 mL Purillex jars were immersed in ethylene glycol-water solution inside the vacuum chamber, with a vacuum applied, and slowly increased to 28.16 in Hg. The vacuum chamber was maintained at this setting for 30 minutes. Then, the containers were removed from the chamber, dried off, and inspected for any sign of leakage into the package. All containers passed the D4991 testing with no leaks observed.

Purillex® PFA Bottles and Jars - ASTM D4991 Test Images





Purillex® PFA Bottles and Jars ASTM D4991 Testing

Conclusion

The ASTM D4991 test method is an important method for testing containers for critical shipping applications. Although the test is a difficult one for standard containers, Purillex bottles and jars easily passed. This is due to their ferrule-style closures, durable construction, and closure torque settings validated by CCIT.

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