



Question related to intermediate storage

How can I safely ship my APIs, bulk drug products, and intermediates from site to site?

Thermo Scientific™ Nalgene™ Biotainer™ bottles have been shown to be effective at shipping frozen contents on dry ice without leaks or damage to the bottle.

Biotainer bottles met the acceptance criteria for shipping and distribution under ASTM 4169, Distribution Cycle 13 Assurance Level II Testing when evaluated by a third party. This protocol simulates the conditions of being shipped by air and truck.



Test details

Nalgene PC and PETG Biotainer bottles ranging in size from 500 mL to 2 L were analyzed in accordance with ANSI/ASQC Z1.4 (ISO 2859). Bottles were preconditioned by freezing to -20°C and exposed to conditions that simulated air shipping and distribution in an insulated shipping container (ISC) using ThermoSafe™ E124 and E66GEN shippers with dry ice (Figure 1). Conditions that were investigated included compression, vibration, drop testing, simulated low-pressure testing, and torque in accordance with the test sequence described by ASTM D4169, Distribution Cycle 13, Assurance Level II. All tests were performed at ambient conditions. Bottles were inspected for any damage or leaks and back-off torque values were noted (Figure 2).

Summary

Nalgene Biotainer bottles withstand typical air and ground shipment while frozen and provide a safe and effective way to ship frozen vaccines and biologics products. Tests show that Biotainer bottles, when packed in an insulated shipper with dry ice, can maintain aqueous product in a frozen condition for 24 hours after exposure to transportation forces and ambient temperatures.

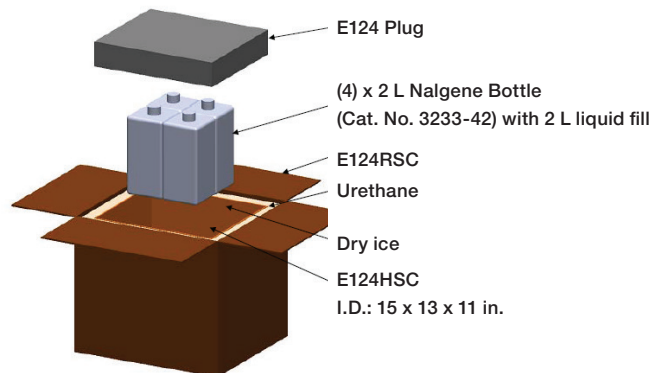


Figure 1. Diagram example of Biotainer bottles and packaging configuration used for evaluation.



Figure 2. Biotainer bottles after completion of vibration, drop, low-pressure, and compression testing.

Cat. No.	3005-70	3110-42	3230-20	3233-42
Description	500 mL PETG	1 L PETG	2 L PETG	2 L PC
Number of samples tested	4 samples, 1 ISC	4 samples, 1 ISC	4 samples, 1 ISC	4 samples, 1 ISC
Visual damage	None	None	None	None
Visual leakage	None	None	None	None
Weight change due to dry ice loss*	7.1 lbs (~73% of the dry ice remained)	7.7 lbs (~61% of the dry ice remained)	13.3 lbs (~70% of the dry ice remained)	13.8 lbs (~69% of the dry ice remained)

* Illustrates shipper integrity and capability to keep container cold during shipping.

To ensure safe usage, customers are advised to test Thermo Scientific™ Nalgene™ bottles and closures under conditions of their planned applications.

Find out more at thermofisher.com/portedclosures

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