

Celsius® FFT Box Shipper Qualification Summary



Technical Note

This document is a summary of qualification testing for Celsius® FFT Box Shippers. These products are intended for domestic or international transport of frozen Celsius® FFT containers.

Product Description

The Celsius® FFT Box Shipper is a robust, qualified solution allowing safe shipment of frozen Celsius® FFT to remote locations. Celsius® FFT Box Shipper is a single-use shipper refrigerated by dry-ice pellets which significantly simplifies biopharmaceuticals supply chain through one-way logistics and the transport of frozen Celsius® FFT to its destination site for thawing.

Celsius® FFT Box Shipper is offered for each of the four sizes of Celsius® FFT: 2 L, 4 L, 6 L and 12 L. There are dedicated Shippers for each Celsius® FFT size: a one-unit and a four-unit shippers are available for the 2 L, 4 L and 6 L Celsius® FFT while the 12L Celsius® FFT has a one-unit version.

The Celsius® FFT Box Shipper has been qualified according to the most stringent regulations for shipping containers: ASTM-D4169 at Assurance Level 1 for mechanical integrity and ISTA 7D extreme summer profile for thermal performance. Altogether, these qualifications run by independant laboratories ensure proper safety and integrity of high-value biopharmaceutical product during frozen shipment.

Scope

This document is applicable to the following Sartorius Stedim Biotech parts:

Part Number	Description
FTH-SM00103-0001	Celsius® FFT 6L 1-Unit Shipper
FTH-SM00103-0002	Celsius® FFT 6L 4-Unit Shipper
FTH-SM00103-0003	Celsius® FFT 4L 1-Unit Shipper
FTH-SM00103-0004	Celsius® FFT 4L 4-Unit Shipper
FTH-SM00103-0005	Celsius® FFT 12L 1-Unit Shipper
FTH-SM00103-0006	Celsius® FFT 2L 1-Unit Shipper
FTH-SM00103-0007	Celsius® FFT 2L 4-Unit Shipper

Description of the Activity

Since it is not possible to anticipate every possible transport route, a set of industry-recognized tests was selected to represent a challenging use scenario. The two main risks to frozen material during transport are mechanical and thermal. Mechanical risks include shock and vibration events encountered during handling, vehicle movement, and loading | unloading. Thermal risks are largely driven by the temperature difference between the interior and exterior of the packaging, especially in hot ambient conditions.

Two families of test standards are referenced in this document for the purpose of evaluating packaging. ASTM D-4169 is used to test against mechanical risks, and ISTA 7D is used to test against thermal risks.

ASTM D 4169

Standard ASTM D 4169-05 “Standard Practice for Performance Testing of Shipping Containers and Systems” was selected for shock and vibration testing. ASTM D 4169 offers three assurance levels – I, II, and III. The ASTM website¹ offers this informal explanation of assurance levels:

“Another unique feature of D 4169 is its flexibility in determining test intensity. There are three levels available for all test methods based on the assurance level one wants to achieve in package performance. For an average level of assurance, one may use Level II with medium test intensities; for highest level of assurance, Level I; and for

the lowest level of assurance, Level III. The level selected is based on product value and end-use, desired level of anticipated damage that can be tolerated, number of units to be shipped, knowledge of the distribution environment, or other criteria. Level II is used by most companies for most goods while manufacturers of such products as high value items or critical care products like medical devices may select Level I for the highest assurance that their packaged product will arrive undamaged. There is undoubtedly a higher cost of packaging incurred to meet the requirements of Level I, but the higher assurance of acceptable performance is deemed worth the added cost.”

Assurance Level I (AL I) was used for all tests described in this document since the contents of the Celsius® FFT Box Shippers are generally valuable. AL I far surpasses the challenges encountered during typical transportation and may reasonably be considered as “worst case”.

Distribution Cycle 2 (DC2) is a custom distribution cycle that permits users to customize the testing to match the distribution environment. For the Celsius® FFT Box Shippers, testing was focused on air and truck transport; no tests were performed for rail or ship transport. The distribution cycle was patterned after Distribution Cycle 12, “Air (intercity) and motor freight (local), over 100 lb (45.4kg), unitized” but dispenses with stacked vibration and low pressure tests. The scenario modeled in the distribution cycle includes forklift handling at origin, truck transport to an airport, air transport (either domestic or international), truck transport to the destination, and forklift handling at the destination.

¹http://www.astm.org/SNEWS/OCTOBER_2004/mckinlay_oct04.html

The test plan was as follows:

Standard ASTM D 4169 – 05

Section	Title	Details	Iteration	Duration
10.3.1.1	Fork lift truck handling	4 edge drops, 2 corner drops	Set 1	
10.3.1.3	Side impact test	4 side impacts	Set 1	
12.4	Random test option	Truck		60 minutes
12.4	Random test option	Air		120 minutes
10.3.1.1	Fork lift truck handling	4 edge drops, 2 corner drops	Set 2	
10.3.1.3	Side impact test	4 side impacts	Set 2	

ISTA 7D

Standard ISTA 7D “Thermal Controlled Transport Packaging for Parcel Delivery System Shipment” was used as a reference when selecting temperature profiles for thermal testing. Note that ISTA 7D was not used in its entirety; shock and vibration components were omitted.

We selected summer (hot shipping & hot receiving) and winter (cold shipping & cold receiving) profiles for 72-hour international expedited airfreight transport plus a 24-hour extension to allow for unexpected delays.

Summer Profile

Temperature	Cycle Period	Cycle Period [h]	Total Time [h]
22 °C	1	4	4
35 °C	2	6	10
30 °C	3	56	66
35 °C	4	30	96

Winter Profile

Temperature	Cycle Period	Cycle Period [h]	Total Time [h]
18 °C	1	4	4
-10 °C	2	6	10
10 °C	3	56	66
-10 °C	4	30	96

On occasion customers ask why shippers are not tested per the new ISTA 7E standard “Testing Standard for Thermal Transport Packaging Used in Parcel Delivery System Shipment”. There are two reasons. First, the

ISTA 7E standard was not available when the testing was started. Second, as there appears to be some uncertainty in the cold chain industry, use of the more mature standard ISTA 7D is prudent while the open questions are resolved.

Mechanical Test Results

Celsius® FFT containers were filled with water and frozen. Shippers were packed out with the nominal quantity of dry ice. Shippers were loaded on a plastic pallet and secured with stretch wrap and plastic banding. Pallets were transported at least 100 Km (62 mi) by truck from the Sartorius facility to the test laboratory where mechanical testing was performed, either Westpak in San Jose, California, USA or VDZ in Dortmund, Germany.

Each pallet was tested per the ASTM D 4169 distribution cycle described in the ASTM D 4169 section above. Following testing, pallets were transported at least 100 Km (62 mi) by truck to the Sartorius facility and unpacked. After thawing, the Celsius® FFT containers were drained, inspected for damage, and leak tested. Each test was considered to pass if there was no damage to the Celsius® FFT container and no significant damage to the shipper.

Results were as follows:

Shipper Type	Load	Fill Shipper	Shippers Pallet	Total	Result
Celsius® FFT 6L 1-Unit FTH-SM00103-0001	Maximum	1×5.9 L	6	6×5.9 L	PASS
	Minimum	1×1.5 L	1	1×1.5 L	PASS
Celsius® FFT 6L 4-Unit FTH-SM00103-0002	Maximum	4×5.9 L	2	8×5.9 L	PASS
	Minimum	2×5.9 L	1	2×5.9 L	PASS
Celsius® FFT 4L 1-Unit FTH-SM00103-0003	Maximum	1×4.0 L	6	6×4.0 L	PASS
	Minimum	1×1.0 L	1	1×1.0 L	PASS
Celsius® FFT 4L 4-Unit FTH-SM00103-0004	Maximum	4×4.0 L	2	8×4.0 L	PASS
	Minimum	2×4.0 L	1	2×4.0 L	PASS
Celsius® FFT 12L 1-Unit FTH-SM00103-0005	Maximum	1×12.0 L	3	3×12.0 L	PASS
	Minimum	1×4.0 L	1	1×4.0 L	PASS
Celsius® FFT 2L 1-Unit FTH-SM00103-0006	Maximum	1×2.0 L	6	6×2.0 L	PASS
	Minimum	1×0.5 L	1	1×0.5 L	PASS
Celsius® FFT 2L 4-Unit FTH-SM00103-0007	Maximum	4×2.0 L	2	8×2.0 L	PASS
	Minimum	2×2.0 L	1	2×2.0 L	PASS

Thermal Test Results

Celsius® FFT containers were filled with water, frozen, and preconditioned to $-55^{\circ}\text{C} \pm 10^{\circ}\text{C}$ in a dry ice chamber. Shippers were packed out with the nominal quantity of dry ice and then subjected to the thermal profiles shown in the ISTA 7D section above. The temperature at center

and corner locations of the Celsius® FFT container(s) was monitored with thermocouples. Each test was considered to pass if all bag temperature measurements remained below -40°C for at least 72 hours.

Results were as follows:

Shipper Type	Load	Fill	Thermal Profile	Result	Time $\leq -40^{\circ}\text{C}$
Celsius® FFT 6L 1-Unit FTH-SM00103-0001	Maximum	1×6.0 L	Summer	PASS	96.0h
			Winter	PASS	96.0h
	Minimum	1×1.5 L	Summer	PASS	96.0h
			Winter	PASS	96.0h
Celsius® FFT 6L 4-Unit FTH-SM00103-0002	Maximum	4×6.0 L	Summer	PASS	96.0h
			Winter	PASS	96.0h
	Minimum	2×6.0 L	Summer	PASS	96.0h
			Winter	PASS	96.0h
Celsius® FFT 4L 1-Unit FTH-SM00103-0003	Maximum	1×4.0 L	Summer	PASS	72.1h
			Winter	PASS	96.0h
	Minimum	1×1.0 L	Summer	PASS	80.4h
			Winter	PASS	96.0h
Celsius® FFT 4L 4-Unit FTH-SM00103-0004	Maximum	4×4.0 L	Summer	PASS	96.0h
			Winter	PASS	96.0h
	Minimum	2×4.0 L	Summer	PASS	96.0h
			Winter	PASS	96.0h
Celsius® FFT 12L 1-Unit FTH-SM00103-0005	Maximum	1×12.0 L	Summer	PASS	96.0h
			Winter	PASS	96.0h
	Minimum	1×3.0 L	Summer	PASS	75.0h
			Winter	PASS	96.0h
Celsius® FFT 2L 1-Unit FTH-SM00103-0006	Maximum	1×2.0 L	Summer	PASS	96.0h
			Winter	PASS	96.0h
	Minimum	1×0.5 L	Summer	PASS	96.0h
			Winter	PASS	96.0h
Celsius® FFT 2L 4-Unit FTH-SM00103-0007	Maximum	4×2.0 L	Summer	PASS	96.0h
			Winter	PASS	96.0h
	Minimum	2×2.0 L	Summer	PASS	96.0h
			Winter	PASS	96.0h

Conclusion


The Celsius® FFT Box Shippers have been tested using well-known mechanical and thermal procedures to demonstrate suitability for use in challenging transport environments.

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