

Shipping Qualification of Mobius® Large Liquid Transportation according to ISTA 3E

Introduction

Safe and efficient transportation of your large bulk liquid substances is critical. These liquids could include sterile water, buffers, media, intermediates, bulk drug substances and final drug products. Therefore, we completed an extensive ISTA shipping validation to provide the safest transportation for your critical bulk liquids.

While looking for a safe and reliable way to transport these significant substances, there are many factors to consider ensuring peace of mind.

Bag Selection: While choosing your bag you must identify a robust film, preferably one with low extractables following BPOG testing guidelines. It is also critical to choose the bag to best fit into your selected carrier.

Carrier Selection: While choosing your carrier, it is important to consider bin durability, collapsible vs rigid container, cleanliness, surface finish, and the ability to stack. Stainless steel bins provide a sturdier and safer way to transport.

Packaging Guidelines

The International Safe Transit Association (ISTA) and American Society for Testing Materials (ASTM) are specific packaging testing guidelines. These tests validate package strength and integrity therefore ensuring real world transfer conditions. The ISTA 3E was most relevant for our shipping test, so we performed that to test our Mobius® Containers.

The ISTA 3 series tests are advanced tests that challenge the capability of the package and product to withstand any transport threats. Procedure 3E is a simulation test for condensed loads of similar packaged products shipped via a full truckload (FTL).



ISTA 3E		
Shock	Incline impact	2.5 mph
Shock	Rotational edge drop	8 inches
Compression	Machine apply and release	Per ASTM D642
	Apply and hold	Per ASTM D642
	Weight and load spreader	Per ASTM D642
Vibration	Random	0.54 Grms

Protocol

The ISTA 3E testing was performed at National Technical Systems (NTS) and verifies that the single-use transportation bag assemblies tested with Mobius Stainless Steel Transport Containers can pass shipping testing per ISTA 3E. The acceptance criteria include the completion of ISTA 3E testing, no leaks in any portion of the bag assemblies, and the shipping container is functional after testing: drain compartment, lid, compression plate, access door are all operational.

To perform this assessment, we used a total of six containers, ranging from 100L to 500L in volume. A variety of different sized batches per container were tested to prove it does not have to be at maximum capacity for a safe transfer. Bag assemblies listed in matrix were filled at NTS using water, leak detecting dye (bright fluorescent- red and green) and scale shown in the **figures 2, 3, and 4.** below. Temperatures were tested at both cold room and ambient temperatures.

ISTA 3E Testing with 500L (yellow) and 200L (pink) Fluid Volume



Figure 2



Figure 3

Representative of the carrier designed used in testing

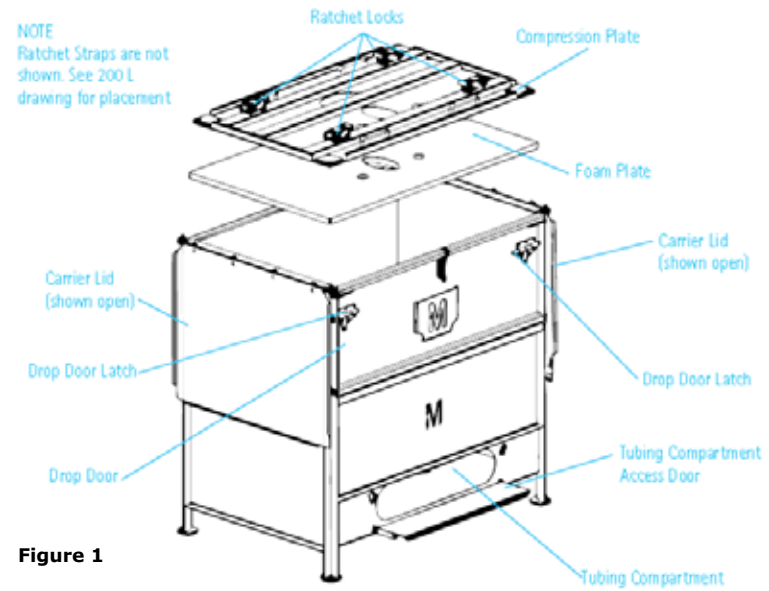


Figure 1

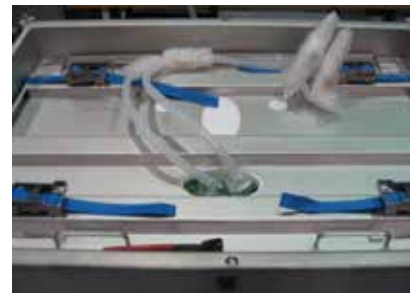


Figure 4

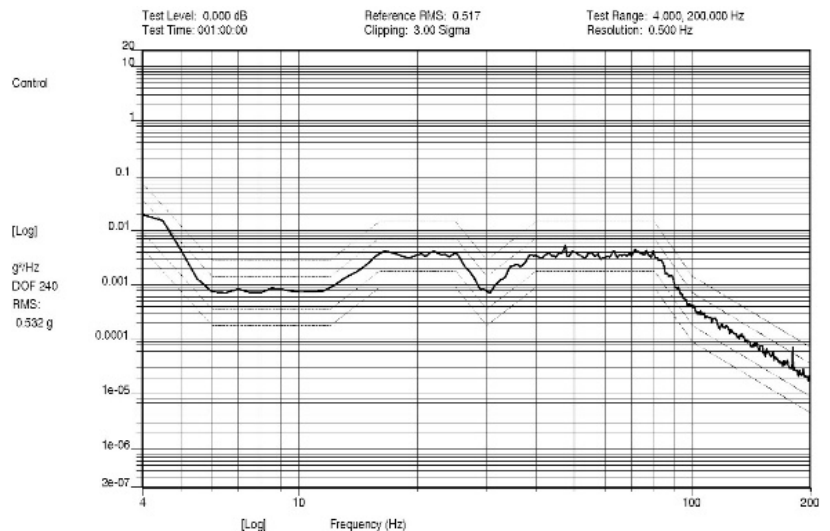
Shock, Rotational Edge Drop of 200L Container



Vibration, Random for 200L Container



Outcome for vertical vibration test



After being tested at a local testing site, it was confirmed that all six tests passed bag assembly inspection leak/drip, container assembly inspection, and integrity test per 00081031TM. See photos besides.

Procedure Test Bag Matrix:

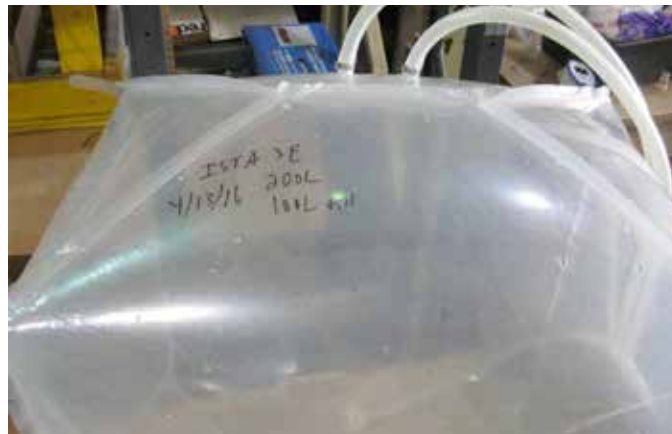
Test No.	Container Size	Fill Volume	Bag Assembly Inspection Leak / Drip (Pass / Fall)	Container Assembly Inspection (Pass / Fall)	Integrity Test per 00081031TM (Pass / Fall)
1A	200L	200L	PASS	PASS	PASS
1B	200L	100L	PASS	PASS	PASS
1C	200L	200L	PASS	PASS	PASS
2A	500L	500L	PASS	PASS	PASS
2B	500L	200L	PASS	PASS	PASS
2C	500L	500L	PASS	PASS	PASS

Integrity Testing				
Test #	Bag Size	Start Pressure (Psi)	End Pressure (Psi)	Result
1A	200L	0.51	0.51	PASS
1B	200L	0.47	0.47	PASS
1C	200L	0.52	0.51	PASS
2A	500L	0.49	0.48	PASS
2B	500L	0.55	0.54	PASS
2C	500L	0.48	0.48	PASS

Results from ISTA 3E Testing

All bags tested went through the same current manufacturing procedure including pre-integrity testing before being filled and packaged. All containers and bags were inspected, disassembled, and drained. There were no leaks or damage in any of the containers or bags and all bags passed post use integrity test. Assemblies were inspected after testing and drained as well. No fluid was observed on the bag assemblies or the containers. The Container and shipping kit provided adequate protection of the bag and assembly components (Lynx® S2S aseptic connectors, NovaSeal™ pinch pipes, etc).

Bags integrity test per 00080263TS. All six bags passed.



All six bags passed integrity test. During the disassembly and draining of the bags, the container drain compartment, lid, compression plate and access door were all opened to confirm functionality. No damage to containers were observed.

The transportation bag assemblies tested with Mobius® Stainless Steel Transport Containers met all the requirements as outlined in protocol 20201468.

Raw Data: completed test matrix, container and bag inspection sheet, integrity testing of bags post test, and frequency (Hz) vs control.

* see appendix for complete data results

Real Time Testing of 3D Large Liquid Transportation System

To accompany the simulation transport testing, a real-time test was conducted. We tested a 200L single-use bag with transport container used to demonstrate real-life shipment transported on a refrigerated truck. The 200L container was filled at a user site in Maryland. During the study, all transportation user guide instructions were followed.

This 200L filled container was shipped 500 miles via road transit to a destination site in Massachusetts.

This container was then inspected and drained, showing no leakage or damage. It also passed the post integrity testing of bags.

Real time testing steps:



Step 1



Step 2



Step 3



Step 4

Conclusion:

It has been confirmed that all six Mobius® bag assemblies passed the ISTA 3E guidelines, including the inspection for leak and drip, container assembly inspection and integrity test per 00081031TM.

These containers also went through a real-time transport test. The container was inspected and drained, and showed no leakage or damage. It also passed the post integrity testing of bags.

Appendix

Container & Bag Inspection Sheet						
Test No.	Container Size	Fill Volume	Item	Area inspected	Result	
1A	200L	200L	Bag	Top of bag	No Leak	
				Bottom of bag	No Leak	
				Drain Compartment	No Leak	
			Container	Lid	No Damage	
				Drain Compartment	No Damage	
				Compression plate	No Damage	
1B	200L	100L	Bag	Top of bag	No Leak	
				Bottom of bag	No Leak	
				Drain Compartment	No Leak	
			Container	Lid	No Damage	
				Drain Compartment	No Damage	
				Compression plate	No Damage	
1C	200L	200L	Bag	Top of bag	No Leak	
				Bottom of bag	No Leak	
				Drain Compartment	No Leak	
			Container	Lid	No Damage	
				Drain Compartment	No Damage	
				Compression plate	No Damage	
2A	500L	500L	Bag	Top of bag	No Leak	
				Bottom of bag	No Leak	
				Drain Compartment	No Leak	
			Container	Lid	No Damage	
				Drain Compartment	No Damage	
				Compression plate	No Damage	
2B	500L	200L	Bag	Top of bag	No Leak	
				Bottom of bag	No Leak	
				Drain Compartment	No Leak	
			Container	Lid	No Damage	
				Drain Compartment	No Damage	
				Compression plate	No Damage	
2C	500L	500L	Bag	Top of bag	No Leak	
				Bottom of bag	No Leak	
				Drain Compartment	No Leak	
			Container	Lid	No Damage	
				Drain Compartment	No Damage	
				Compression plate	No Damage	
					Access door (500L Only)	No Damage

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References:

ISTA: General Simulation Performance Tests
<https://ista.org/docs/3Eoverview.pdf>

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