Purillex® Fluoropolymer Bottle Freeze Mapping

APPLICATION NOTE

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APPLICATION NOTE

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ABSTRACT

Placing Purillex fluoropolymer bottles in -85°C freezer

The ability to freeze bulk drug substance (BDS) at temperatures at or below -80°C is critical to the bioprocess industry – as are rapid and efficient freezing and thawing processes. Bottles are a container of choice for freezing due to their durability and convenience, as well as their compatibility with standard laboratory equipment, shelving and racking, and standard shipping containers.

Fluoropolymer bottles are an excellent choice for BDS processes as they do not change structurally when flash frozen. Therefore, containers manufactured from fluoropolymers have the ability to not only survive flash freezing but to retain the same shape and functionality as at room temperature.

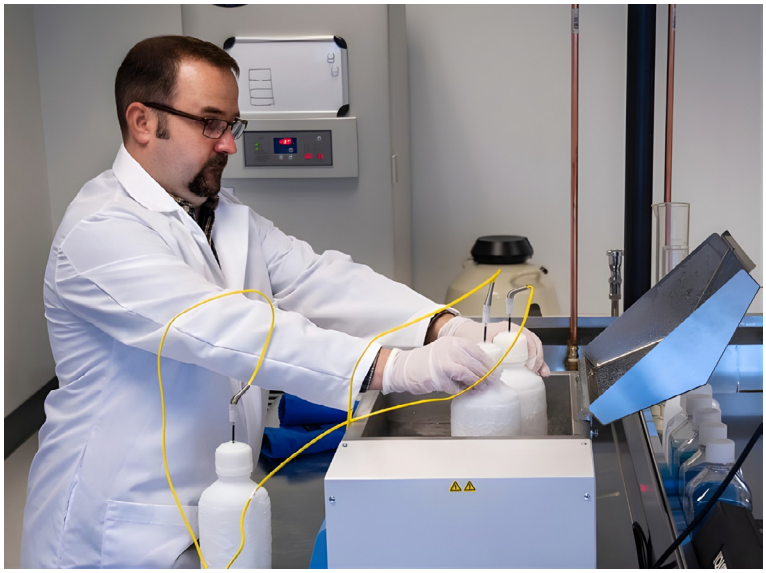
Another key consideration when selecting a container for flash freezing are the methods used to freeze and thaw the container contents during use. Bags and other flexible containers often require dedicated freezing systems with custom designed supportive and protective racking in order to successfully freeze and thaw. Bottles, on the other hand, can be frozen and thawed using standard laboratory equipment - such as upright freezers and water baths - and do not require support or protection during these processes. This application note outlines a study performed to determine the flash freeze and water bath thaw time for a range of Savillex fluoropolymer bottle sizes using a standard laboratory freezer and water bath.

TEST OVERVIEW - FREEZE AND THAW

TEST PREPARATION	**Materials:** • Savillex Purillex® PFA and ETFE bottles • Upright -85°C freezer • 18 L laboratory water bath • 4-channel datalogger with Type K thermocouples Three bottles of each size (50, 100, 250, 500, 1000 and 2000 mL)

TEST PREPARATION (CONTINUED)	were filled to nominal volume using water, then each was monitored using thermocouples during flash freezing to -80°C followed by a water bath thaw to 20°C using the two procedures outlined below. Six separate test runs were performed - one for each bottle size.
TEST PROCEDURE	**Freeze Procedure:** 1. Fill bottle to rated capacity with water 2. Insert 1/16” TC probe into bottle at controlled depth measured from top of closure 3. Place bottle in -85°C freezer 4. Record data for 24 hours **Thaw Procedure:** 1. Remove bottles from freezer 2. Immediately place bottles in 37°C preheated recirculating water bath 3. Record data until water within bottle is completely thawed

Filling bottles to rated capacity with water



Placing bottles in 37°C preheated recirculating water bath

TEST RESULTS - FREEZE AND THAW

Table 1 and charts 1 and 2 summarize the flash freeze and thaw times for each bottle size tested. No frozen product remained in the bottles at the “Thaw to 20°C” time points.

Table 1: Summary of times for flash freeze and thaw

Bottle Volume (mL)	Freeze to -80°C (min)	Thaw to 20°C (min)
50	144	29
100	171	32
250	266	59
500	378	86
1000	539	142
2000	766	191

Chart 1: Summary of time to flash freeze to -80°C

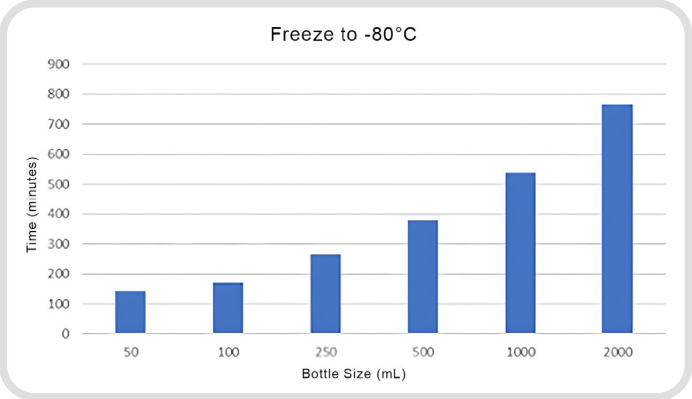
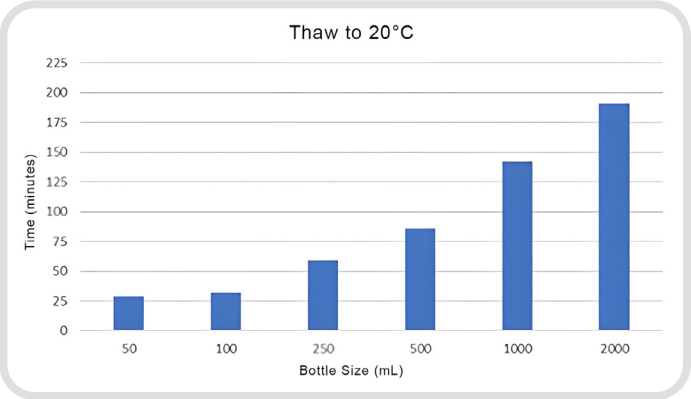


Chart 2: Summary of time to thaw to 20°C



Charts 3 and 4 are sample temperature charts for freezing and thawing of the 1000 mL bottle size. The freeze and thaw process yielded relatively smooth temperature curves for all bottles sizes.

Chart 3: Summary of temperature for freezing a 1000 mL bottle

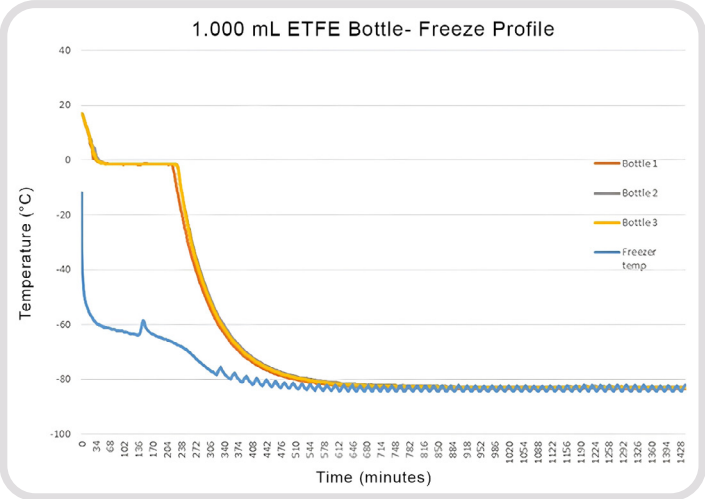
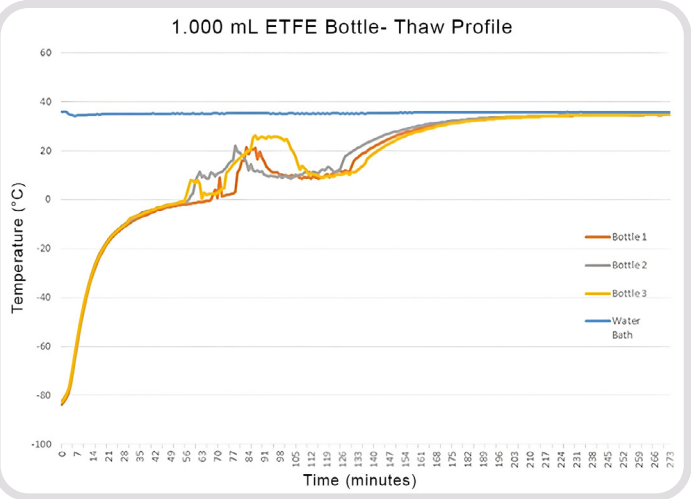


Chart 4: Summary of temperature for thawing a 1000 mL bottle

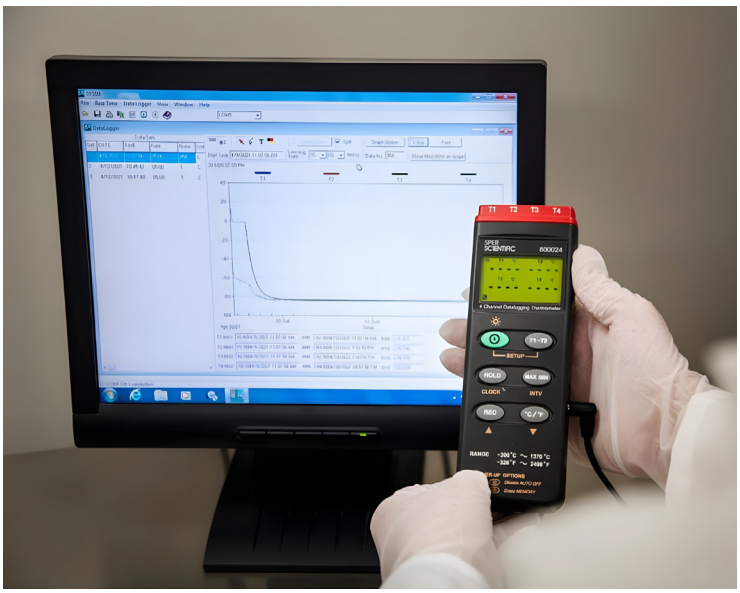


During the thaw testing of the 1000 mL and 2000 mL bottle sizes, the temperatures could be seen to fluctuate once above 0°C. These temperature fluctuations were verified to be the result of ice melting and mixing with heated water within the bottle during the thawing process. The temperature curves again smoothed out once all ice had melted.

CONCLUSIONS

Results indicate that bottle freezing and thawing is a consistent process with little variation between units. However, some temporary variability was seen during the thaw process due to ice retention in the larger bottle sizes. Although this test used water as the freezing medium and a limited number of units per test, actual freeze and thaw testing may vary based on fluid density, number and size of bottles used, bottle orientation within the freezer and water bath, freezer cooling capacity and water bath heating capacity.

It is recommended that this testing only be used as a guideline, and additional testing may be required in order to determine freeze and thaw times for specific products and processes.



Uploading recorded data from a 4-channel datalogger with Type K thermocouples

CLICK HERE TO LEARN MORE ABOUT PURILLEX BOTTLES AND PLACE ORDERS ONLINE.

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