Savillex Technical Note

CO_2 Ingress Testing on Purillex® PETG Square Media Bottles

Management Summary

Carbon dioxide (CO_2) ingress into polymeric containers can be an issue when storing or shipping pH-sensitive drug products, biologics, and other critical liquid materials. When storing or shipping these products, they can be packed in dry ice, which is the solid form of CO_2.

Dry ice does not melt into a liquid, but rather sublimates from a solid to a gas, which has the potential to enter the container either through the bulk of the material or through the container/closure interface. If there is headspace in the container and CO_2 gas enters, it has the potential to adversely affect the container contents by lowering the pH due to the formation of carbonic acid with container contents.

Thanks to their lightweight, shatter-resistant nature, PETG (Polyethylene Terephthalate Glycol) bottles are an ideal option for scientists looking to avoid the issues that lead to CO_2 ingress. They also boast exceptional gas barrier properties, making them an excellent choice for pharmaceutical and biologics manufacturing applications, including:

- Media and buffer storage
- Sample collection
- Buffer preparation
- Process intermediates
- Transportation of reagents

Various sizes of Purillex PETG Square Media Bottles

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In order to more fully characterize Purillex PETG bottles, Savillex took the opportunity to perform supporting verification testing in terms of CO_2 ingress.

Testing was performed to determine if a pH shift could be measured in 1L Savillex Purillex PETG Square Media Bottles (both sterile and non-sterile) filled to nominal volume with phosphate buffered saline (PBS) after exposure to dry ice for a minimum of 60 hours. It is generally accepted that a pH shift of ±0.1 can be attributed to the freezing process itself. Any pH shift greater than 0.1 could indicate potential CO_2 ingress.

Based on the results of this test, no bottles from either group (dry ice or standard freezer) exhibited a pH shift greater than ±0.1, highlighting Purillex PETG Square Media Bottles as a robust container/closure system capable for use in dry ice storage or shipping applications.

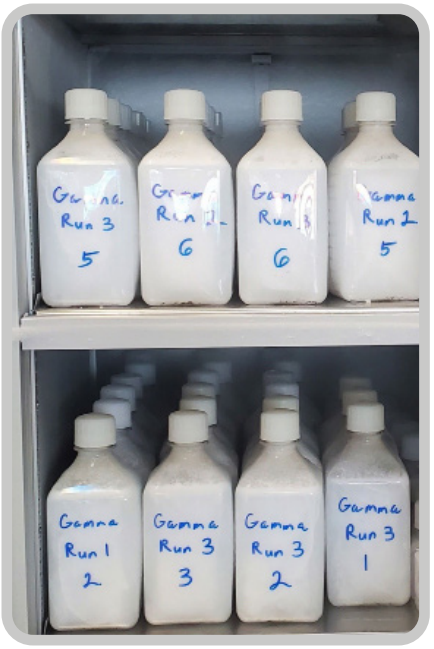

Figure 1: 1L Purillex PETG Bottless in upright freezer at -85°C (control bottles)

Results and Discussion

A set of six (6) sterile and six (6) non-sterile 1L Purillex PETG Bottles from each of three (3) different manufacturing runs were sampled. The PBS solution pH was measured, the bottles were filled to nominal volume, and the closures were torqued to 30 in-lb (Savillex recommended torque value). All bottles were placed in an upright freezer at -85°C for a minimum of 48 hours. After 48 hours, three (3) sterile and three (3) non-sterile bottles from each of the three (3) different manufacturing runs were transferred to a bunker containing dry ice for a minimum of 60 hours (Figures 1 and 2). The bottles were then removed from the freezer and dry ice bunker and allowed to thaw for a minimum of 120 hours prior to measuring pH.

In addition to the 1L bottles tested, six (6) 250 mL bottles were used as positive controls. A 1/8” hole was drilled in the closures, and all bottles were placed in the upright freezer at -85°C for a minimum of 48 hours. Three (3) of the bottles were then placed in a bunker containing dry ice for a minimum of 48 hours to ensure exposure to CO_2 gas. The bottles were then removed from the freezer and dry ice bunker and allowed to thaw for a minimum of 120 hours prior to measuring pH.

Figure 2: 1L Purillex PETG Bottles packed in dry ice (note that only bottle closures can be seen in the image)

After 120 hours, bottles were removed from the dry ice bunker, and the control bottles from the upright -85°C freezer and allowed to thaw to room temperature at which time final pH measurements were recorded.

See Tables 1 and 2 for test results from both 1L bottle groups, and Tables 3 and 4 for positive control results.

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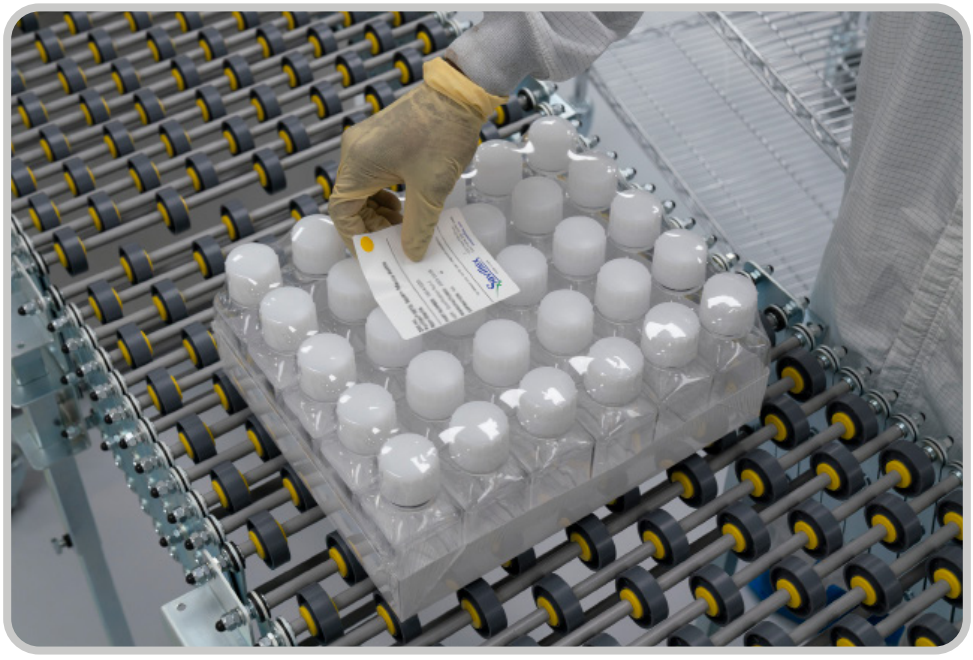
Table 1: PETG Bottle pH Data, -85°C Freezer (Control Bottles)

Bottle Size	Manufacturing Run	Number	pH at Fill (21°C)	pH After Thaw (21°C)	ΔpH
1000 mL	Run 1	1	7.57	7.54	-0.03
1000 mL	Run 1	2	7.54	7.56	0.02
1000 mL	Run 1	3	7.54	7.53	-0.01
1000 mL	Run 2	1	7.56	7.54	-0.02
1000 mL	Run 2	2	7.54	7.55	0.01
1000 mL	Run 2	3	7.54	7.53	-0.01
1000 mL	Run 3	1	7.54	7.54	0
1000 mL	Run 3	2	7.54	7.53	-0.01
1000 mL	Run 3	3	7.54	7.54	0
1000 mL Gamma	Run 1	1	7.53	7.57	0.04
1000 mL Gamma	Run 1	2	7.54	7.57	0.03
1000 mL Gamma	Run 1	3	7.54	7.54	0
1000 mL Gamma	Run 2	1	7.52	7.56	0.04
1000 mL Gamma	Run 2	2	7.54	7.56	0.02
1000 mL Gamma	Run 2	3	7.54	7.57	0.03
1000 mL Gamma	Run 3	1	7.54	7.55	0.01
1000 mL Gamma	Run 3	2	7.54	7.52	-0.02
1000 mL Gamma	Run 3	3	7.54	7.53	-0.01



Shrink-wrapped package of Purillex PETG Square Media Bottles

Table 2: PETG Bottle pH Data, Dry Ice

Bottle Size	Manufacturing Run	Number	pH at Fill (21°C)	pH After Thaw (21°C)	ΔpH
1000 mL	Run 1	4	7.54	7.57	0.03
1000 mL	Run 1	5	7.54	7.55	0.01
1000 mL	Run 1	6	7.54	7.56	0.02
1000 mL	Run 2	4	7.54	7.54	0
1000 mL	Run 2	5	7.54	7.56	0.02
1000 mL	Run 2	6	7.54	7.56	0.02
1000 mL	Run 3	4	7.54	7.54	0
1000 mL	Run 3	5	7.54	7.54	0
1000 mL	Run 3	6	7.53	7.55	0.02
1000 mL Gamma	Run 1	4	7.54	7.57	0.03
1000 mL Gamma	Run 1	5	7.54	7.56	0.02
1000 mL Gamma	Run 1	6	7.54	7.52	-0.02
1000 mL Gamma	Run 2	4	7.54	7.54	0
1000 mL Gamma	Run 2	5	7.54	7.57	0.03
1000 mL Gamma	Run 2	6	7.54	7.56	0.02
1000 mL Gamma	Run 3	4	7.53	7.52	-0.01
1000 mL Gamma	Run 3	5	7.54	7.54	0
1000 mL Gamma	Run 3	6	7.54	7.51	-0.03

Table 3: PETG Positive Control Bottle pH Data, -85°C Freezer

Bottle Size	Manufacturing Run	Number	pH at Fill (21°C)	pH After Thaw (21°C)	ΔpH
250 mL with 1/8” hole	Run 1	7	7.39	7.40	0.01
250 mL with 1/8” hole	Run 1	8	7.39	7.40	0.01
250 mL with 1/8” hole	Run 1	9	7.40	7.42	0.02

Table 4: PETG Positive Control Bottle pH Data, Dry Ice

Bottle Size	Manufacturing Run	Number	pH at Fill (21°C)	pH After Thaw (21°C)	ΔpH
250 mL with 1/8” hole	Run 1	10	7.39	6.06	-1.33
250 mL with 1/8” hole	Run 1	11	7.39	6.18	-1.21
250 mL with 1/8” hole	Run 1	12	7.40	6.02	-1.38

Based on the results of this test, no bottles from either group (dry ice or standard freezer) exhibited a pH shift greater than ±0.1, highlighting Savillex Purillex PETG Square Media Bottles as a robust container/closure system capable for use in dry ice storage or shipping applications.

Positive controls performed as expected, with the 250mL bottles with 1/8” hole in the closure and packed in dry ice exhibiting a significant drop in pH as compared to the other bottle groups (Figure 3). Positive control bottles in the -85°C freezer did not exhibit a drop in pH.

The boxplot in Figure 3 is a graphical representation of all pH data collected for all test groups. Note the significant difference between the positive control in dry ice and all other groups, thus confirming the efficacy of the test method.

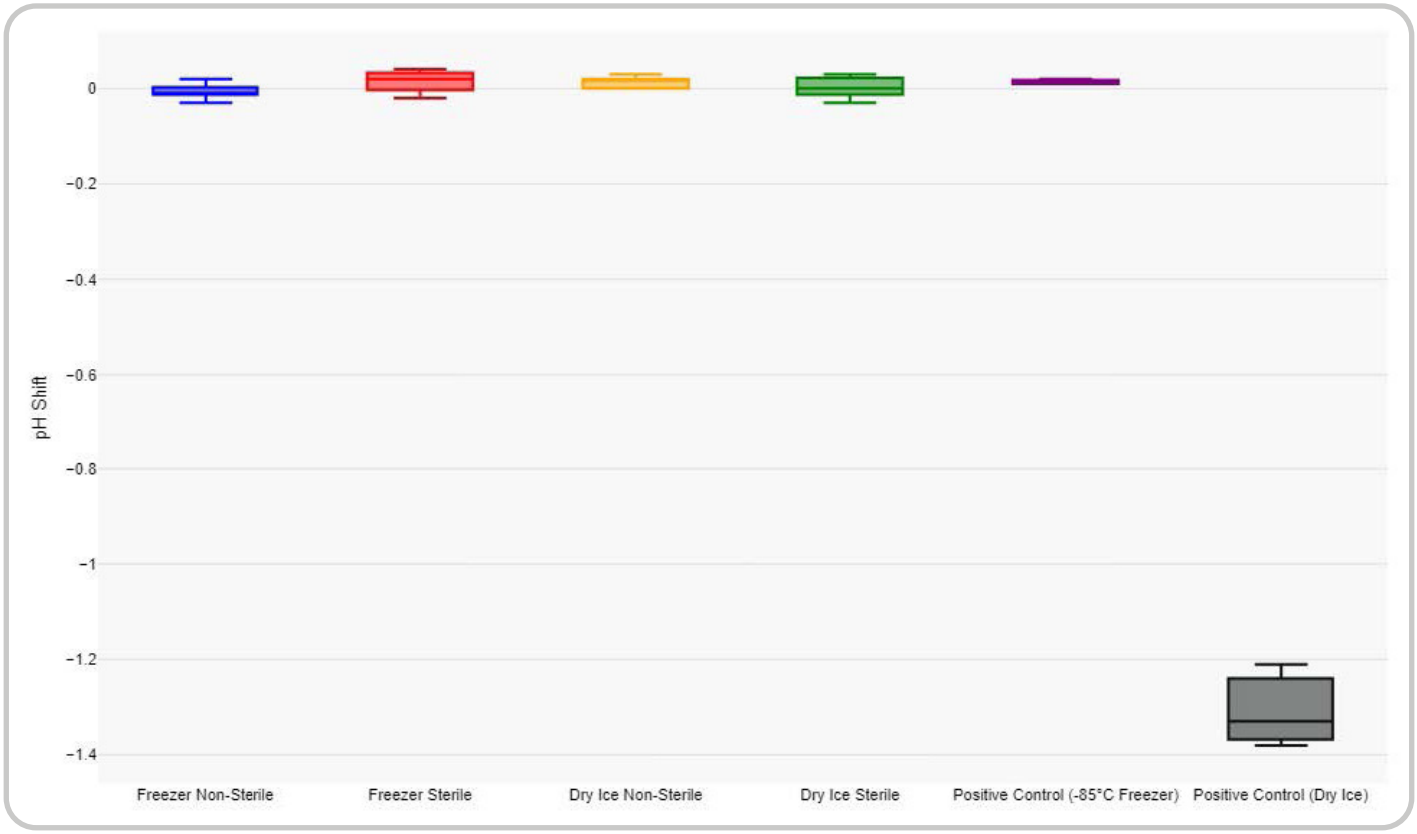


Figure 3: pH Shift in Savillex Purillex PETG Bottles after freezing in dry ice and conventional freezer

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Equipment and Materials Used

Equipment	Model/Part No.	Manufacturer	Calibration	Calibration Due	Lot
NuAire Freezer	NU-99338JGA	NuAire	11.8.23	11.8.24	N/A
Purillex PETG Bottle	160-04-1000-S	Savillex	N/A	N/A	6-4-1L-S-00001
Purillex PETG Bottle	160-04-1000	Savillex	N/A	N/A	
Phosphate Buffered Saline Solution	472594	Lifecycle Biotechnologies	4.5.22 (mfg. date)	4.23.24 (exp. date)	220941420
Benchtop pH Meter	A211	Thermo Scientific	Verify before use		N/A

Purillex PETG Square Media Bottle manufacturing run

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10321 West 70th St. | Eden Prairie, MN 55344-3446 USA | Phone: 952.935.4100
Email: info@savillex.com | www.savillex.com