

Aramus™ Single-use Bags

Compatibility with dimethyl sulfoxide (DMSO)

MANAGEMENT SUMMARY

Entegris customers have asked about chemical compatibility of Aramus™ assemblies with dimethyl sulfoxide (DMSO), which is commonly used as a cryopreservant in the cell and gene therapy (CGT) markets.

The objective of this test was to determine chemical compatibility of the Aramus bag material via mechanical testing (burst and tensile strength) after exposure to 100% DMSO after different lengths of time (T = 0 (control), 24 hours, 7 days, and 21 days) at room temperature.

Aramus 50 mL (SU-2D-0.050S1-L12B) bags were tested for mechanical properties (burst and tensile strength) both before and after exposure to 100% DMSO. All bags were exposed to 42 kGy gamma irradiation prior to beginning the test.

Based on the results of the test, it appears that Aramus bag integrity was not significantly affected by exposure of 100% DMSO up to 21 days. In addition to tensile and burst data, it should also be noted that visual inspection yielded no discoloration after exposure to 100% DMSO after 21 days.

Future testing would most likely include larger sample sizes, and perhaps longer-term storage.

RATIONALE

Entegris customers have requested compatibility information of Aramus bags with DMSO, which is commonly used as a cryopreservant in the cell and gene therapy (CGT) markets.



OBJECTIVE

Determine chemical compatibility of the Aramus bag material via mechanical testing (burst and tensile strength) after exposure to 100% DMSO after different lengths of time (T = 0 (control), 24 hours, 7 days, and 21 days) at room temperature.

SUMMARY AND CONCLUSION

Aramus 50 mL (SU-2D-0.050S1-L12B) bags were tested for mechanical properties (burst and tensile strength) both before and after exposure to 100% DMSO. All bags were exposed to 42 kGy gamma irradiation prior to beginning the test.

Based on the results of these limited tests, it appears that Aramus bag integrity was not significantly affected by exposure of 100% DMSO up to 21 days. Tensile testing showed consistent results above 23 in•lbf/in³ (ksi). Burst testing showed consistent results ≥ 12 psi. In addition to tensile and burst data, it should also be noted that visual inspection yielded no discoloration after exposure to 100% DMSO after 21 days.

Future testing would most likely include larger sample sizes, and perhaps longer-term storage.

PRODUCT TESTED

Twenty-four, 50 mL Aramus assemblies with BarbLock® retainers. Three units per time interval (T = 0, T = 24 hours, T = 7 days, and T = 21 days) x two tests (tensile and burst).

Part number SU-2D-0.050S1-L12B, Appendix 1.

Table 1. Sample receipt and test dates

	Date
Samples received	April 29, 2019
Test started	May 2, 2019
Test completed	May 24, 2019

RESULTS

All test samples were gamma irradiated (42 kGy) prior to testing. Results of the tensile and burst testing are shown in the following Tables and Figures.

In addition to tensile and burst data, it should also be noted that visual inspection yielded no discoloration after exposure to 100% DMSO after 21 days.

Two tensile strips from each bag were tested and were taken from the film itself, not on the welds, Figure 1.

Table 2. Tensile test results (ksi)

	Control	24 hour	7 day	21 day
Average (n = 3)	24.77	24.78	23.43	24.68
% Change (from control)	N/A	0.03	-5.40	-0.36

Tensile Test – 50 mL Aramus Bag Assemblies

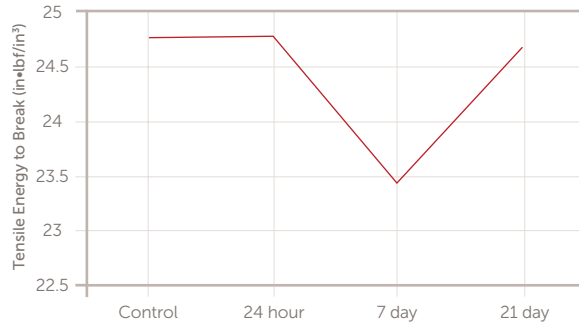


Figure 1. Tensile energy-to-break test results

Exposure of the Aramus assemblies to 100% DMSO did not appear to greatly impact tensile properties, but it is currently unknown as to the reason for the drop in tensile energy at break for the 7-day samples.

Figure 2 shows the sample orientation for the tensile test.

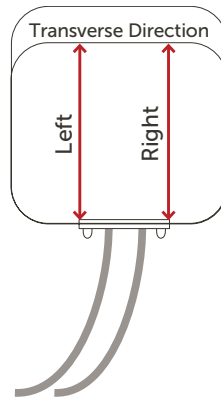


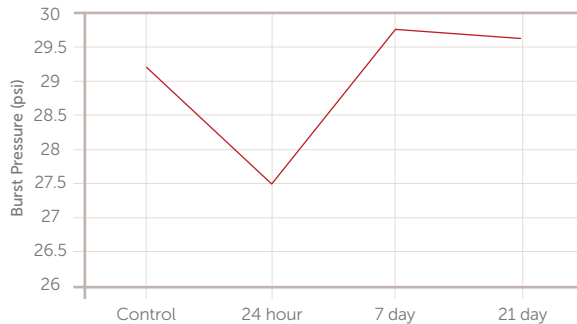
Figure 2. Bag sampling method

Burst testing was performed to determine burst pressure after DMSO exposure. Internal production specifications require burst pressures for 50 mL bags to be ≥12 psi. All Aramus assemblies yielded passing results, as burst pressures were >12 psi. Results of the burst testing are shown in Table 3 and Figure 3.

Table 3. Tensile test results (psi)

	Control	24 hour	7 day	21 day
Average (n = 3)	29.20	27.50	29.77	29.63
% Change (from control)	N/A	-5.82	1.94	1.48

Burst Test – 50 mL Aramus Bag Assemblies



Based on the results of this test, it appears exposure of Aramus assemblies to 100% DMSO for up to 21 days does not significantly reduce mechanical properties in terms of tensile strength or burst pressure when compared to assemblies not exposed to DMSO.

Figure 3. Average burst pressure test results post DMSO exposure

Additionally, no discoloration of the assemblies or leakage was observed over the course of the test.

PROCEDURES

Test Method

1. Sample fill

- Ensure samples have been exposed to 42 kGy dose of gamma irradiation. All samples are to be filled with DMSO under a well-ventilated hood in the Chaska, Minnesota laboratory. Set aside six samples to test for tensile and burst. These will be the T = 0 (control) samples.
- Use Luer lock syringes to fill each sample with 30 mL of DMSO solution (100%). Enough to cover entire interior surface.
- Filled bags are to remain in the well-ventilated lab hood up until time interval has been completed (24 hour, 7 day, 21 day).
- Drain DMSO from the samples and proceed with tensile and burst tests.

2. Tensile test

- Entegris WI-12906

3. Burst test

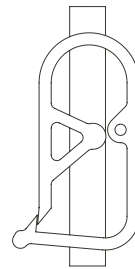
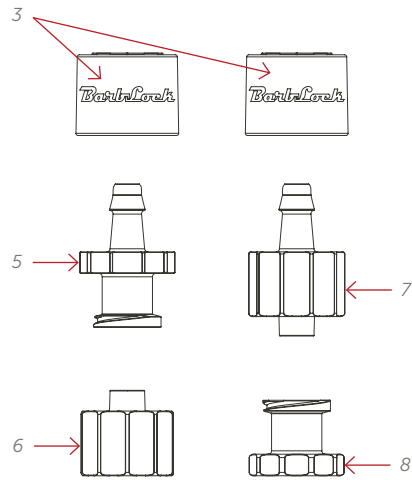
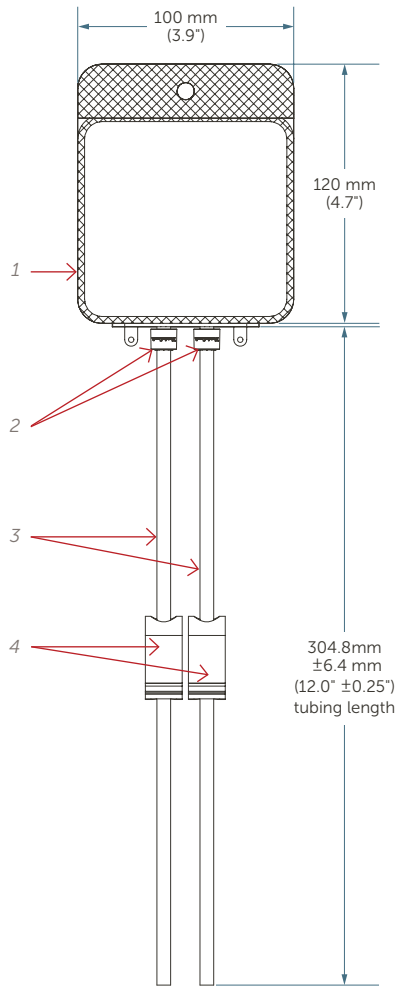
- Entegris WI-03228

EQUIPMENT/INSTRUMENTATION

Table 4. Equipment/instrumentation used

Equipment/instrument	ID	Last calibrated	Calibration due
Instron® tensile tester	20262682	10/05/2018	10/05/2019
Pressure transducer – burst tester	21619516	10/11/2018	10/11/2019
DMSO – Fisher Scientific	D128-1 (Lot 187334)	N/A	N/A

**APPENDIX 1: SU-2D-0.050S1-L12B ASSEMBLY
USED FOR DMSO TESTING**



Pinch clamp orientation

Item	Description	Quantity
1	Aramus subassembly, 50 mL	1
2	Sleeve and collet (BarbLock), 1/8"	4
3	Tubing, Tygon®, platinum-cured silicone, 1/8" diameter, ft.	2
4	Clamp, tube, pinch type, 12 mm ID	2
5	Luer, female, thread style, 1/8"	1
6	Plug, luer, male	1
7	Luer, male, thread style, 1/8"	1
8	Cap, luer, female, luer thread	1

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