

# 50-ML STABILITY CONTAINER ASSEMBLY FOR FROZEN STORAGE DURING DRUG SUBSTANCE DEVELOPMENT

## Product Description

The 50-milliliter (ml) stability container assembly supports the GORE STA-PURE Flexible Freeze Container product line intended for handling, transport and storage of biopharmaceutical intermediates, after freezing at -86°C (-123°F). The 50-ml container is engineered from the same materials of construction (film, port, and tubing) as all container sizes within the GORE STA-PURE Flexible Freeze Container product line.

The connector options are:

- Outer tubes: Female Luer lock or Colder AsepticQuik® S
- Center tube: Needle free swabable valve

## Common Applications

The GORE STA-PURE Flexible Freeze Containers are intended for storing and transporting biopharmaceutical intermediates but not limited to:

- Gene Therapy
- Viral Vectors
- Vaccines
- Antibody Drug Conjugates (ADCs)
- Monoclonal antibodies

The user is most knowledgeable about the composition of the formulation, bulk substance, or aqueous solution and is therefore responsible for validating that the Freeze Container is suitable for use in the intended application.

## Technology

GORE STA-PURE Flexible Freeze Containers are engineered with a proprietary high purity polytetrafluoroethylene (PTFE) composite film. They are designed to provide high strength and durability at low temperatures.



## Key Features and Benefits

### Robust film and innovative container design\*

- Proven strength and durability at frozen temperatures
- Maintain frozen container integrity after multiple freeze/thaw cycles

### Fluoropolymer container materials of construction

- Low extractables profile with chemically inert materials
- Minimize risk of drug interaction or contamination

### Available ready-to-use according to user specifications

- Assemblies sterilized with tubing and connectors\*\*
- Assemblies constructed of the same fluid path contact materials as assemblies within the GORE STA-PURE Flexible Freeze Container product line

\* Patent pending

\*\* Contact Gore for configuration options

## Quality and Compliance

GORE® STA-PURE® Flexible Freeze Container Assemblies are manufactured in a manner that adheres to relevant current Good Manufacturing Practices (cGMP) as defined in the Gore PharmBio Products' quality system which is certified to ISO 13485 and ISO 15378.

Manufacturing, assembly, inspection, and packaging of the Flexible Freeze Container Assemblies are conducted in a controlled environment that is maintained to ISO Class 7 requirements.

GORE STA-PURE Flexible Freeze Containers are manufactured following the appropriate material and regulatory requirements. Please contact Gore for current compliance standards.

## Extractables

Gore has conducted an extractables study based on guidelines put forth by the BioPhorum Operations Group (BPOG) as stated in their Users Requirements Pack. Please contact Gore for more information.

## Sterilization

Freeze Container Assemblies are sterilized using ethylene oxide (EO) prior to shipment and meet the Sterility Assurance Level per ISO 11135.

Irradiation sterilization methods such as gamma or electron beam should never be used because they may damage or degrade the mechanical and barrier properties of the Container.

## Stability Container Testing

Containers filled with phosphate-buffered saline (PBS) solution were frozen in a blast freezer for a minimum of 24 hours with a set point of -86°C (-123°F). After testing, the containers were integrity tested by vacuum decay and visual inspection.

|                     |                                                                                                        |
|---------------------|--------------------------------------------------------------------------------------------------------|
| Freeze/Thaw         | Stored in a freezer and thawed in a water bath for 5 cycles                                            |
| Biocompatibility    | USP <87> Biological Reactivity Tests In Vitro<br>USP <88> Biological Reactivity Tests In Vivo Class VI |
| Bacterial Endotoxin | USP <85> Bacterial Endotoxin Tests limits, ≤ 0.25 EU/mL                                                |
| Particulates        | USP <788> Particulate Matter in Injections, Small Volume Injection Limits for a 50-ml container        |
| Shelf Life          | Based on 3-year real time aging at ambient temperature and humidity                                    |

After testing, the containers were integrity tested by vacuum decay and visual inspection.

## Film Performance

| Property                        | Test Standard | Value                               |
|---------------------------------|---------------|-------------------------------------|
| Tensile Strength*               | ASTM D882     | 202 MPa MD<br>96 MPa TD             |
| Transparency*                   | ASTM D1003    | 55.6%<br>Transmission Haze          |
| Water Vapor Transmission Rate** | ASTM F1249    | 0.013 cc/(100 in <sup>2</sup> /day) |
| O <sub>2</sub> Permeability**   | ASTM D3985    | 55 cc/(100 in <sup>2</sup> /day)    |
| CO <sub>2</sub> Permeability**  | ASTM F2476    | 113.8 cc/(100 in <sup>2</sup> /day) |

MD machine direction; TD transverse direction; MPa megapascal; cc cubic centimeter

\*Sample size selected per ASTM standard. Average result reported.

\*\* Samples from 3 lots and 2 replicates per lot were tested. Average result reported.

## Materials of Construction

| Description     | Material of Construction                 |
|-----------------|------------------------------------------|
| Container film* | Polytetrafluoroethylene (PTFE) composite |
| Port*           | Fluorinated ethylene propylene (FEP)     |

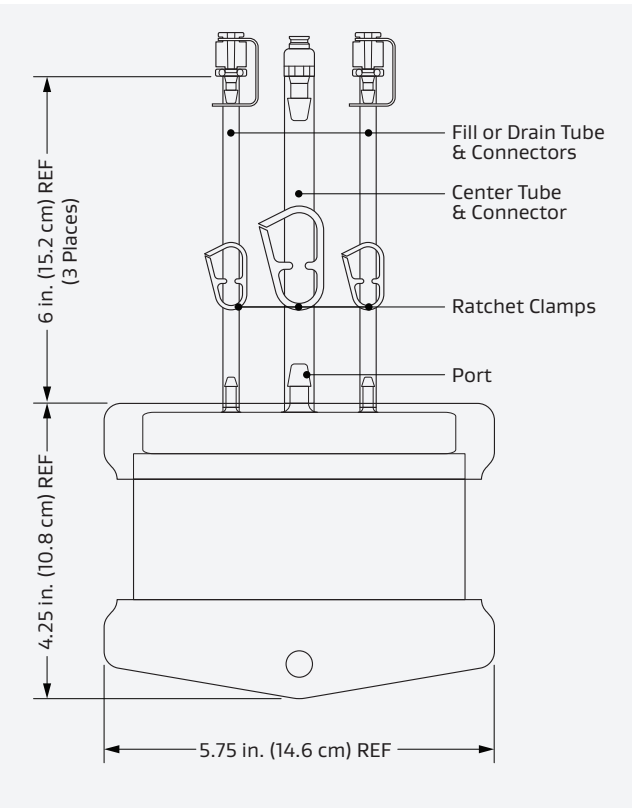
\* Fluid contact surface

## Barrier Wrap Performance

If carbon dioxide (CO<sub>2</sub>) or oxygen (O<sub>2</sub>) permeation are a concern in the application, an optional vacuum heat-sealable secondary Barrier Wrap is available to minimize ingress. The Wrap fully encloses the Stability Container Assembly, including tubing.

| Fluid                             | Test Standard | Permeability                              |
|-----------------------------------|---------------|-------------------------------------------|
| Oxygen (O <sub>2</sub> )          | ASTM D3985    | < 0.0003 cc/(100 in <sup>2</sup> /24 hrs) |
| Carbon Dioxide (CO <sub>2</sub> ) | ASTM F2476    | < 0.0645 cc/(100 in <sup>2</sup> /24 hrs) |
| Water Vapor                       | ASTM F1249    | < 0.001 g/(100 in <sup>2</sup> /24 hrs)   |

## Dimensions/Design



## Ordering Information

|                           | Part Number                        |                    |                                    |                    |
|---------------------------|------------------------------------|--------------------|------------------------------------|--------------------|
|                           | P/N GS00614                        | P/N GS00615        | P/N GS00616                        | P/N GS00617        |
| Center Connector          | Needle free swabable valve         |                    |                                    |                    |
| Fill or Drain Connector   | Female Luer Lock with tethered cap | Colder AseptiQuik® | Female Luer Lock with tethered cap | Colder AseptiQuik® |
| Tubing Material           | Silicone                           | Silicone           | TPE                                | TPE                |
| Center Tubing Size (ID)   | 6.35 mm (0.25 in)                  |                    |                                    |                    |
| Fill or Drain Tubing Size | 3.175 mm (0.125 in)                |                    |                                    |                    |

## Packaging Information

The Freeze Container Assemblies are sterilized and packaged inside two TYVEK® pouches prior to shipment.

## Gore PharmBIO Products

Our technologies, capabilities, and competencies in fluoropolymer science are focused on satisfying the evolving product, regulatory, and quality needs of pharmaceutical and bioprocessing customers, and medical device manufacturers. GORE STA-PURE Flexible Freeze Container, like all products in the Gore PharmBIO Products portfolio, are tested and manufactured under stringent quality systems. These high-performance products provide creative solutions to our customers' design, manufacturing, and performance-in-use needs.

NOT INTENDED FOR USE in medical device or food contact applications or with radiation sterilization.

All technical information and advice given here is based on our previous experiences and/or test results. We give this information to the best of our knowledge, but assume no legal responsibility. Customers are asked to check the suitability and usability of our products in the specific applications, since the performance of the product can only be judged when all necessary operating data is available. Gore's terms and conditions of sales apply to the purchase and sale of the product.

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**Americas | W. L. Gore & Associates, Inc.**  
402 Vieve's Way, Elkton, MD 21921 • USA  
T +1 410 506 1715 Toll-free (US) 1 800 294 4673  
Email [pharmbio@wlgore.com](mailto:pharmbio@wlgore.com)

[gore.com/pharmbio](https://gore.com/pharmbio)

**Europe | W. L. Gore & Associates, GmbH**  
Wernher-von-Braun-Strasse 18, 85640 Putzbrunn, Germany  
T +49 89 4612 3456 Toll free 0 800 4612 3456  
Email [pharmbio\\_eu@wlgore.com](mailto:pharmbio_eu@wlgore.com)

