GORE® STA-PURE®
Flexible Freeze Container
50-ml Stability Container Assembly

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 AseptiQuik® 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
- Mimimize 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

Together, improving life

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 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 96 MPa TD
Transparency*	ASTM D1003	55.6% Transmission Haze
Water Vapor Transmission Rate**	ASTM F1249	0.013 cc/(100 in^2/day)
O_2 Permeability**	ASTM D3985	55 cc/(100 in^2/day)
CO_2 Permeability**	ASTM F2476	113.8 cc/(100 in^2/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)

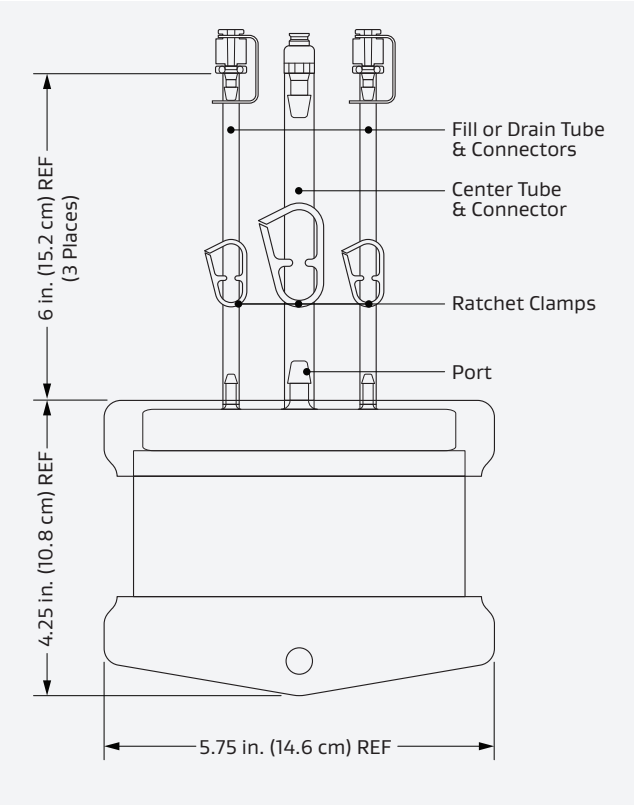
*Fluid contact surface

Barrier Wrap Performance

If carbon dioxide (CO_2) or oxygen (O_2) 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_2)	ASTM D3985	< 0.0003 cc/(100 in²/24 hrs)
Carbon Dioxide (CO_2)	ASTM F2476	< 0.0645 cc/(100 in²/24 hrs)
Water Vapor	ASTM F1249	< 0.001 g/(100 in²/24 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.

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