



GORE® STA-PURE

FLEXIBLE FREEZE CONTAINER

Durable Single-use Containers for Cold Chain Handling of Bulk Drug Substance

REDUCE RISK OF PRODUCT LOSS DURING FROZEN HANDLING, STORAGE AND TRANSPORT

PRODUCT DESCRIPTION

Single-use GORE STA-PURE Flexible Freeze Containers are intended for handling, transport and storage of frozen bulk drug substances, after freezing at -86°C (-123°F). Unlike other bags that may become brittle and fragile when frozen, GORE STA-PURE Freeze Containers resist cracks, breaks or leaks if accidentally dropped. The enhanced durability combined with a low extractables profile makes these containers an ideal solution for biopharmaceutical applications.

COMMON APPLICATIONS

GORE STA-PURE Flexible Freeze Containers are intended for storing and transporting bulk drug substances including but not limited to:

- 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

Patented* 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.

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 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 statements.



KEY FEATURES AND BENEFITS

Robust film and innovative container design*

- Proven strength and durability at frozen temperatures
- Maintain frozen film integrity after impact and flex cycles
- 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 silicone tubing and connectors**
- Sized to fit most standard freeze/thaw equipment (blast and plate)
- Additional hard-shell carrier† and barrier wrap available

NOTE: See Container Testing table (page 2) for performance test parameters

EXTRACTABLES

Gore is undertaking an extractables study based on guidelines put forth by the BioPhorum Operations Group (BPOG) as stated in their User Requirements Pack. Contact Gore for more information.

* Patent EP3174514; additional patents pending in the US and EU.

** Contact Gore for configuration options

† Patent pending



Gore STA-PURE

FLEXIBLE FREEZE CONTAINER

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), or in a plate freezer for a minimum of 4 hours at a set point of -70°C (-94°F). After freezing, the containers were tested for frozen impact durability, performance after freeze/thaw cycling, and after long-term storage.

Frozen Impact Durability	Frozen and dropped from height of 3 feet (91.4 cm) onto concrete floor
Freeze/Thaw	Stored in a freezer and thawed in a water bath for 5 cycles
Long-Term Frozen Storage	Stored for 12 months

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

ADDITIONAL TESTING

Biocompatibility	USP <87> Biological Reactivity Tests In Vitro USP <88> Biological Reactivity Tests In Vivo Class VI
Bacterial Endotoxin	USP <85> Bacterial Endotoxin limits
Particulates	USP <788> Particulate Matter in Injections

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)
O2 Permeability**	ASTM D3985	55 cc/(100 in ² /day)
CO2 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.

STERILIZATION

Freeze Container Assemblies are sterilized using ethylene oxide (EO) prior to shipment and meet the Sterility Assurance Level per ISO11135.

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.

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.

gore.com/pharmbio

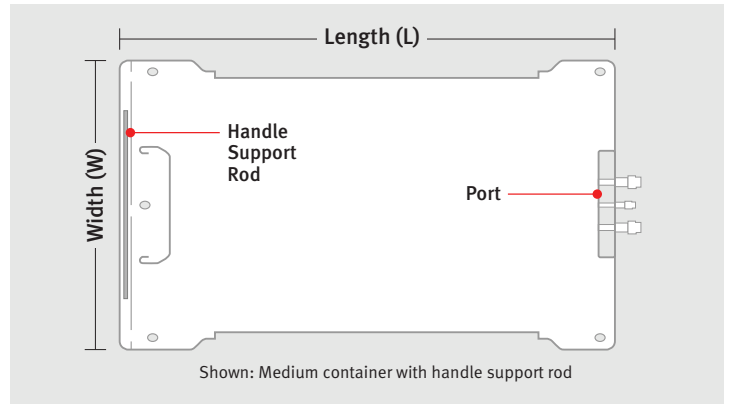
MATERIALS OF CONSTRUCTION

Description	Material of Construction
Container film*	Polytetrafluoroethylene (PTFE) composite
Port*	Fluorinated ethylene propylene (FEP)
Handle support rod**	Stainless steel

* Fluid contact surface

** Medium and Small container only

DIMENSIONS/DESIGN



CONTAINER SIZES

Size	Dimensions (W x L)	Freezing Method	Maximum Fill Volume
Sample	5 x 6 in (12.7 x 15.2 cm)	Suitable for plate or blast freezers	50 milliliter (mL)
Small	8 x 17.5 in (20.3 x 44.5 cm)	plate blast	2.5 Liter (L) 2.5 Liter (L)
Medium	12 x 18 in (30.5 x 45.2 cm)	plate blast	4.25 Liter (L) 5.0 Liter (L)
Large	25 x 16 in (63.5 x 40.6 cm)	plate blast	10 Liter (L) 12 Liter (L)

Optional Hard-shell Carrier and Barrier Wrap sold separately.

Contact Gore for tubing and connector options.

PACKAGING INFORMATION

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

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Not intended for use in medical device or food contact applications or with radiation sterilization.

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