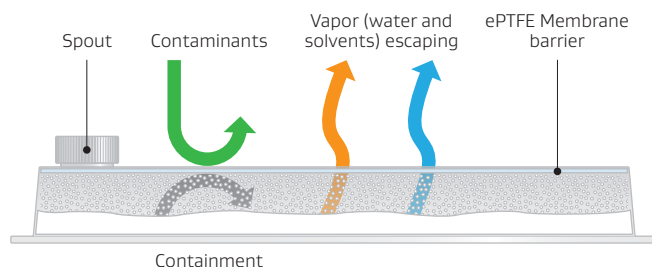


Single-use disposable containers for bulk lyophilization

CONTAIN API AND HIGH POTENCY API DURING LYOPHILIZATION

Product Description

GORE LYOGUARD Freeze-Drying Trays are fully enclosed, single-use, disposable containers that use expanded polytetrafluoroethylene (ePTFE) membrane technology to contain and protect liquid or lyophilized active pharmaceutical ingredient (API) during the entire freeze-drying process.



The ePTFE tray surface is chemically inert, biocompatible and includes a convenient fill cap. The flexible, thin film tray bottom closely conforms to dryer shelves for efficient and uniform heat transfer.

These autoclavable trays are designed to be direct replacements to open trays and are compatible with most freeze-drying processes.



Key Features and Benefits

Product Contact Surfaces

- Reduce risk of fly-out or ejection during lyophilization
- Minimize risk of inadvertent spills and associated cleanups
- Reduce freeze dryer cleaning costs and eliminates tray cleaning

Easily integrate with your process

- Direct replacement for open or covered trays or containers
- Convenient fill cap for efficient filling operations
- Compatible with most freeze-drying processes and equipment
- Can be sterilized by autoclave

Common Applications

- Bulk lyophilization of polypeptides, oligonucleotides, other APIs and HPAPIs, proteins, intermediate drug substance, and biologics
- Process development
- Clinical phases and full scale manufacturing

Material of Construction

Product Contact Surfaces

- Polypropylene
- Expanded polytetrafluoroethylene (ePTFE) membrane

Tray Manufacturing Environment and Quality

Assembly, final inspection and packaging of the GORE® LYOGUARD® Tray are conducted in a cleanroom maintained to ISO Class 7 requirements.

GORE LYOGUARD Freeze-Drying Trays 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 ISO13485 and ISO15378.

GORE LYOGUARD Trays are 100% visually inspected for defects in workmanship and visible contamination.

Dimensions

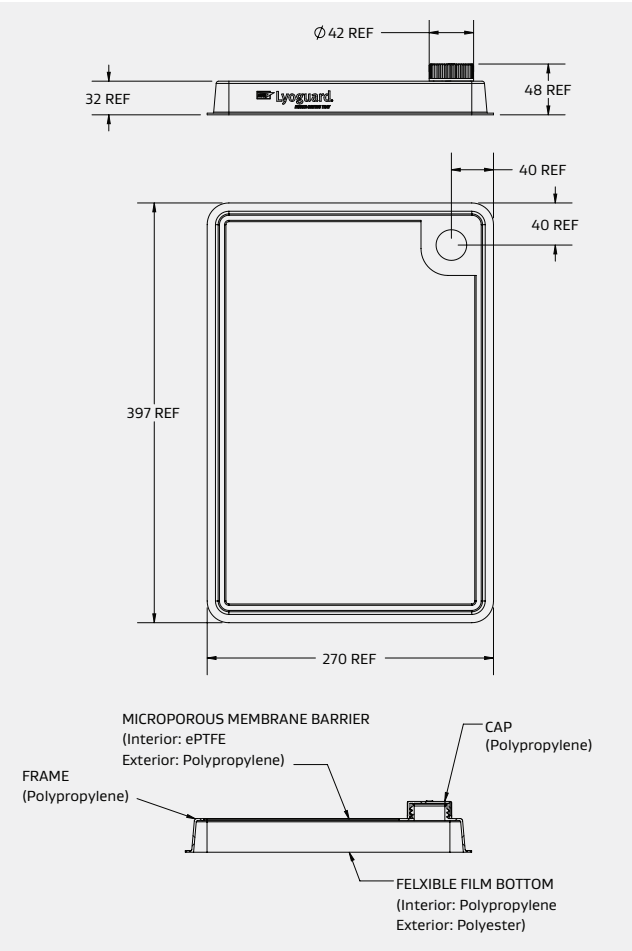


FIGURE 1: Dimensions of LGT2000 Trays (mm)

Performance Data Summary

GORE LYOGUARD Freeze-Drying Trays meet the requirements of the following*:

Biocompatibility	USP <87> Biological Reactivity Test In Vitro USP <88> Biological Reactivity Test In Vivo, Class VI
Bacterial Endotoxin	USP <85> Bacterial Endotoxin limits
Physicochemical	Relevant physicochemical tests as defined in Plastic Packaging Systems for Pharmaceutical Use USP <661.2>
Particulates	USP <788> Particulate Matter in Injections — Microscope Particle Count Test for Large-Volume Injections
Barrier Testing	The adequacy of the trays to maintain a sterile barrier was demonstrated through the Aerosol Challenge and Talc Challenge tests.

*Detailed test procedures and results are available in the most recent GORE LYOGUARD Freeze-Drying Trays Validation Guide.

Operation

Chemical Compatibility

All product contact surfaces are composed of PTFE or polypropylene. Both polymers are chemically inert and have a high degree of compatibility with a variety of fluids.

As with other processing aids, the user, who is most knowledgeable about the formulation of the product, is responsible for ensuring the compatibility of their formulation with GORE® LYOGUARD® Trays.

Recommended Tray Fill Volume	Recommended Operating Temperature
Maximum volume: 1800ml	Maximum temperature: 125°C (257°F)
Minimum volume: 200 ml	Minimum temperature: -60°C (-76°F)

Sterilization

The GORE LYOGUARD Tray may be steam sterilized once (if necessary), using a moist heat, pre-vacuum autoclave cycle. Temperatures should not exceed 125°C (257°F). See the Autoclave Sterilization Guidelines for more detailed information. Irradiation sterilization methods such as gamma or electron beam should never be used because they may alter the mechanical and barrier properties of the product.

Storage

Storage Recommendation

Store in original packaging at temperatures between 10-40°C (50-104°F) with humidity less than 65%.

Shelf Life

When properly stored, it is recommended to use GORE LYOGUARD Freeze-Drying Trays within two years of the date of manufacture.

Ordering Information

Part	Part Number	Minimum Order Quantity	Accessories Sold Separately
Tray	LGT2000	15 Trays (1 box)	
Foil Pouch	FP30031	50 Pouches	Foil pouches are recommended for product stored in trays after lyophilization
Crossbar	P229	10 Bars	Crossbars are recommended for use during autoclaving

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 LYOGUARD Freeze-Drying Trays, 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.

The GORE LYOGUARD Tray is neither classified nor regulated as a medical device and is not subject to FDA regulation.

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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