



# LYOGUARD®

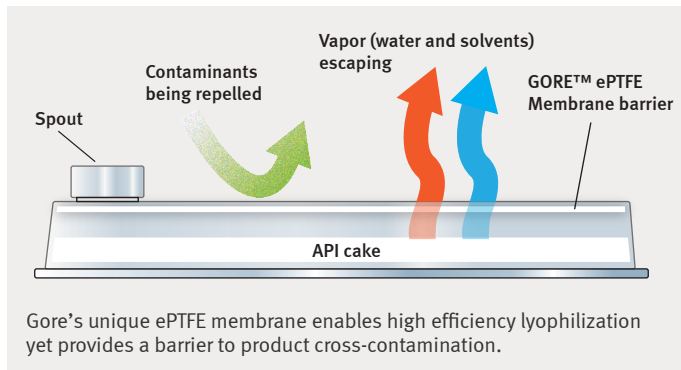
**FREEZE-DRYING TRAYS**

*Single-use disposable  
containers for bulk  
API lyophilization*

## Protect and contain product during lyophilization

### Product Description

GORE® LYOGUARD® Freeze-Drying Trays are fully enclosed, single-use, disposable containers that use a unique ePTFE membrane technology to both prevent cross-contamination and fly-out, and enable the free exchange of moisture vapor during lyophilization.



The ePTFE tray surface is chemically inert, biocompatible and includes a convenient fill cap. The flexible, thin-film polypropylene 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.

### Common Applications

- Bulk API lyophilization up to 1800 ml
- Formulation research and development
- Clinical phases and full scale manufacturing

### Material of Construction

#### Product Contact Surfaces

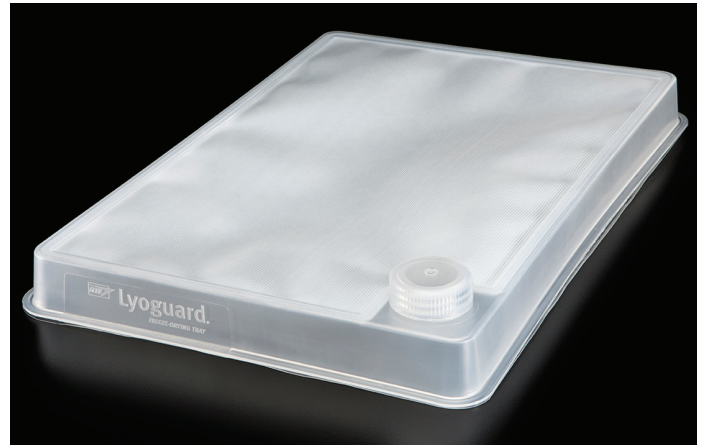
- Polypropylene
- GORE™ expanded polytetrafluoroethylene (ePTFE) membrane

#### Other External Materials

- Polyester

### Regulatory Information

The GORE® LYOGUARD® Tray is intended for use as a processing aid in the production of materials that are frequently subject to FDA regulation. The regulatory status of the end product resulting from a manufacturing process, such as a pharmaceutical, does not transform a manufacturing apparatus into a medical device. The GORE® LYOGUARD® Tray is neither classified nor regulated as a medical device.



### Key Features and Benefits

#### Protective ePTFE barrier membrane

- Offers high moisture vapor transmission rate
- Developed for freeze-drying processes
- Reduces product cross-contamination
- Limits exposure to API with reduced fly-out
- Reduces or eliminates freeze dryer cleaning costs
- Provides optimized throughput with shorter cycle times

#### Single-use, disposable trays fit standard freeze dryers

- Enables the use of existing equipment during processing
- Provides an alternative to tray covers or open trays

#### Bio-compatible, chemically inert materials of construction

- Suitable for pharmaceutical lyophilization

#### Thin flexible bottom film and tray frame

- Enables uniform and efficient heat transfer

### Tray Manufacturing Environment and Quality

Assembly operations for the GORE® LYOGUARD® Trays are conducted in an ISO 8 clean room with particle monitoring to ensure that the room is operating to at least ISO 7 (class 10,000) during operation. Final inspection and packaging are conducted in a controlled environment.

GORE® LYOGUARD® Freeze-Drying Trays are manufactured in a manner that adheres to relevant current Good Manufacturing Practices (cGMP), as defined in a quality system certified to ISO9001, ISO13485, and ISO15378.

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



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## Performance Data Summary

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

<b>Biocompatibility</b>	USP <87> Biological Reactivity Test In Vitro USP <88> Biological Reactivity Test In Vivo, Class VI
<b>Bacterial Endotoxin</b>	USP <85> Bacterial Endotoxin limits
<b>Physicochemical</b>	Physicochemical Tests set forth in the Test Method section and Expanded Extracts (Solvents) per USP <661>, Physicochemical Testing
<b>Particulates</b>	USP <788> Particulate Matter in Injections for Large Volume Parenterals
<b>Barrier Testing</b>	The adequacy of the trays to maintain a sterile barrier was demonstrated through the <i>Aerosol Challenge and Talc Challenge</i> tests.

The details of test procedures and results are available in the *GORE® LYOGUARD® Freeze-Drying Trays Validation Guide*.

## Operating Conditions

### Chemical Compatibility

All product contact surfaces are composed of polytetrafluoroethylene 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.

### Sterilization

The GORE® LYOGUARD® Tray may be steam sterilized once (if necessary), using a moist heat, pre-vacuum autoclave cycle. Refer to *GORE® LYOGUARD® Freeze-Drying Trays Validation Guide* for more information.

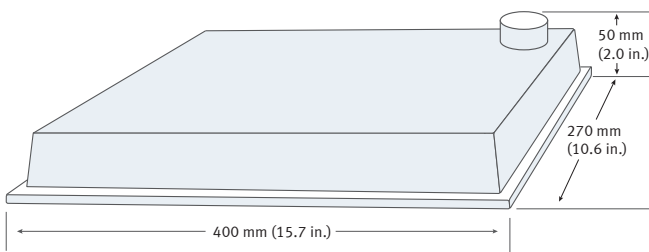
### Recommended Tray Fill Volume

Maximum volume: 1800ml  
Minimum volume: 200 ml

### Recommended Temperature

Maximum temperature: 125°C (257°F)  
Minimum temperature: -60°C (-76°F)

## Dimension and Design



## 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.

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

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