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.
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.

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Performance Data Summary

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

<table>
<thead>
<tr>
<th>Biocompatibility</th>
<th>USP &lt;87&gt; Biological Reactivity Test In Vitro</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial Endotoxin</td>
<td>USP &lt;85&gt; Bacterial Endotoxin limits</td>
</tr>
<tr>
<td>Physicochemical</td>
<td>Physicochemical Tests set forth in the Test Method section and Expanded Extracts (Solvents) per USP &lt;661&gt;, Physicochemical Testing</td>
</tr>
<tr>
<td>Particulates</td>
<td>USP &lt;78B&gt; Particulate Matter in Injections for Large Volume Parenterals</td>
</tr>
<tr>
<td>Barrier Testing</td>
<td>The adequacy of the trays to maintain a sterile barrier was demonstrated through the Aerosol Challenge and Talc Challenge tests.</td>
</tr>
</tbody>
</table>

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) |

**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.

Dimension and Design

- **Minimum Order Quantity**
  - 15 Trays (1 box)
  - 50 Pouches
  - 10 Bars

**Ordering Information**

<table>
<thead>
<tr>
<th>Part</th>
<th>Part Number</th>
<th>Accessories Sold Separately</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tray</td>
<td>LGT2000</td>
<td>Foil pouches are recommended for product stored in trays after lyophilization</td>
</tr>
<tr>
<td>Foil Pouch</td>
<td>FP30031</td>
<td>Crossbars are recommended for use during autoclaving</td>
</tr>
<tr>
<td>Crossbar</td>
<td>P229</td>
<td></td>
</tr>
</tbody>
</table>

**Biocompatibility**

USP <87> Biological Reactivity Test In Vitro

USP <85> Biological Reactivity Test In Vivo, Class VI

USP <88> Biological Reactivity Test In Vivo, Class VI

**Bacterial Endotoxin**

USP <78B> Particulate Matter in Injections for Large Volume Parenterals

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