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.

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

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

Tray Manufacturing Environment and Quality

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

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.
Performance Data Summary

**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.

<table>
<thead>
<tr>
<th>Recommended Tray Fill Volume</th>
<th>Recommended Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum volume: 1800ml</td>
<td>Maximum temperature: 125°C (257°F)</td>
</tr>
<tr>
<td>Minimum volume: 200 ml</td>
<td>Minimum temperature: -60°C (-76°F)</td>
</tr>
</tbody>
</table>

**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 damage or degrade 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**

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

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