GORE® LYOGUARD® Freeze-Drying Trays

Protect active pharmaceutical ingredients during lyophilization

The Biggest Risks of Conventional Freeze-Drying Trays

The lyophilization process creates multiple vulnerabilities for product loss and contamination that can impact your bottom line as a pharmaceutical manufacturer.

Common issues include:

- Product fly-out or ejection compromising yield during processing
- Inadvertent spills resulting in extensive cleanup and production delays
- Metal trays requiring thorough cleaning and validation after each use
- Handling and cleaning exposing operators to potential safety hazards

Product Description

GORE LYOGUARD Freeze-Drying Trays are single-use, disposable containers that replace traditional open metal trays in tray freeze-drying applications. These fully enclosed trays contain and protect your active pharmaceutical ingredients (API) during the entire lyophilization process.

The key features of our trays include:

- **Containment technology:** The microporous ePTFE membrane barrier allows efficient sublimation while keeping product securely inside, reducing the risk of product fly-out or ejection even with light, fluffy powders.
- **Single-use design:** Eliminates cross-contamination concerns between batches due to ineffective cleaning, especially in multi-use facilities.
- **Seamless integration:** Provides a direct replacement for open or covered trays, with a convenient fill cap to minimize the risk of spills. Fits easily with most freeze-drying equipment.



Proven Performance

In rigorous testing, GORE LYOGUARD Freeze-Drying Trays demonstrated 100% effectiveness as a barrier to aerosolized microbial ingress and egress, preventing product and lyophilizer contamination.

Manufacturing Quality Assurance

GORE LYOGUARD Freeze-Drying Trays are manufactured under stringent quality systems that adhere to relevant current Good Manufacturing Practices (cGMP). Assembly, final inspection, and packaging are conducted in a controlled environment maintained to ISO Class 7 requirements.

Quality assurance includes:

- ISO 13485 and ISO 15378 certified quality management systems
- Complete visual inspection of every tray for defects and contamination
- Testing to ensure USP<85> Bacterial Endotoxin standards are met
- Confirmation of USP <87> and <88> Class VI biocompatibility requirements
- Testing to ensure USP <788> Particulate Matter standards are met

Learn More

Protect your valuable API throughout the lyophilization process. Contact our team today to learn how GORE LYOGUARD Freeze-Drying Trays can reduce risk during your manufacturing process.

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 Freeze-Drying 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 terms and conditions of sales apply to the purchase and sale of the product.

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