LYOGUARD®

FREEZE-DRYING TRAYS

Application Questionnaire

Date (MM/DD/YY):		Gore Field Sales Assoc.	
Company		Site Location Name	
Street Address		City, State, Zip, Country	
Contact Name		Job Role	
Phone		Email	

1. Type of product:

☐ mAb ☐ Bacteria ☐ Glycoprotein ☐ Probiotic ☐ Allergy Medication
☐ Bulk API ☐ Oligonucleotide ☐ Protein ☐ API (Chemical) ☐ Collagen
☐ Peptide ☐ Recombinant Protein ☐ Other (Please specify): _____

2. When introduced into the tray, product is considered: ☐

If other, please define: _____

3. Final product's route of administration: ☐

If other, please define: _____

If parenteral, will the final product that contains this freeze-dried product be sterile filtered or otherwise terminally sterilized?
☐ Yes ☐ No ☐ N/A

4. What is the primary solvent being used? _____ Concentration (%) _____

5. **CLEANLINESS:** Assembly operations for the GORE® LYOGUARD® Freeze-Drying Trays are conducted in an ISO 8 cleanroom with particulate monitoring to ensure the room is operating at an ISO 7 (Class 10,000) level or lower during operation. Final inspection and packaging is conducted in a controlled environment. Please confirm that this assembly environment is acceptable for this application? ☐ Yes ☐ No

For the GORE® LYOGUARD® Freeze-Drying Trays (as delivered) is the internal surface cleanliness stated below acceptable in this application?

Particulate[1]**:** limit 12 ≥ 10µm, limit 2 ≥ 25µm: ☐ Yes ☐ No **Endotoxin**[2]**:** < 20 eu/tray: ☐ Yes ☐ No
Bioburden: Tray is supplied non-sterile: ☐ Yes ☐ No

1. Ref: USP ‹788› Particulate Matter In Injections Microscopic Particle CountTest for Large-Volume Injections, fill volume 1.8L of water
2. Ref: USP ‹85›Bacterial Endotoxin, rinse of product contact surfaces

6. **ANIMAL DERIVED MATERIALS:** Animal derived materials are used in the manufacture of GORE® LYOGUARD® Freeze-Drying Trays. Please confirm this is acceptable for this application? ☐ Yes ☐ No

Note: A technical bulletin is available upon request to clarify any concerns or questions that may arise from users of the trays.

7. **STERILIZATION AND USE:** Irradiation sterilization methods such as gamma or electron beam should never be used because they may damage or degrade the mechanical properties of the tray. Steam sterilization is the only validated method of sterilization. Please confirm steam sterilization will be the only method used: ☐ Yes ☐ No
The minimum temperature rating for the tray is -60°C. Will the tray be exposed to temperature < -60°C during freeze-drying? ☐ Yes ☐ No

8. **STORAGE AND TRANSPORT (POST FREEZE-DRYING):** Gore does not have testing to support the long term storage and transportation of product in trays. Please confirm that if product will be stored and/or transported in trays that the process and product integrity will be validated. ☐ Yes ☐ No

Comments:

Americas | W. L. Gore & Associates, Inc.
402 Vieve's Way • Elkton, MD 21921 • USA
Phone: +1 410 506 1715 • Toll-free (US): 1 800 294 4673
Email: pharmbio@wlgore.com

gore.com/pharmbio

Europe | W. L. Gore & Associates GmbH
Wernher-von-Braun-Strasse 18 • 85640 Putzbrunn, Germany
Phone: +49 89 4612 3456 • Toll Free: 0 800 4612 3456
Email: pharmbio_eu@wlgore.com

Creative Technologies Worldwide

PB2524-Rev3-PS-US-JAN18