

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, final inspection, and packaging of the GORE® LYOGUARD® Freeze-Drying Trays are conducted in a controlled environment maintained to ISO Class 7 requirements. Please confirm that this 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**<sup>1</sup>: limit 12 ≥ 10µm, limit 2 ≥ 25µm:    Yes    No      **Endotoxin**<sup>2</sup>: < 20 eu/tray:    Yes    No

**Bioburden:** Tray is supplied non-sterile:    Yes    No

1. Ref: USP <788> Particulate Matter In Injections Microscopic Particle Count Test for Large-Volume Injections, fill volume 1.8L of water

2. Ref: USP <85> Bacterial Endotoxin, rinse of product contact surfaces

**6. 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

**7. STORAGE AND TRANSPORT (POST FREEZE-DRYING):** Gore does not have testing to support the long term storage and transportation of product in trays, while liquid, frozen, or in dry form. 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:**

