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Together, improving life

December 2025

To Whom It May Concern:

RE: Extractable Report for GORE® LYOGUARD® Freeze-Drying Trays

The attached report is an extractables study performed on the GORE® LYOGUARD® Freeze-Drying Tray ("the Product"). The extraction design was based on guidance provided in United States Pharmacopeia and National Formulary <665> "Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products". The testing outlined in the report was performed on the Product fluid path. The test results are a point in time based on two replicates, with two lots, and do not represent a claim for each future production lot. The Product is manufactured and packaged in a controlled environment, which is maintained to ISO Class 7 requirements 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 ISO 13485 and ISO 15378.

GORE® LYOGUARD® Freeze-Drying Trays are not intended for storage of liquid drug substances with the scope of use limited to the removal of solvent under lyophilization conditions. Therefore, the 24-hour extraction time point was chosen for this study according to USP <665>, Table 1. Since the drug substance and associated solvent system is briefly maintained at ambient conditions during filling followed by lyophilization, the aqueous extractions were not performed as the extraction power of this polar solvent is considered inconsequential for this short period. The more non-polar 50% ethanol solvent has much greater extraction power and was the focus of this study. Per USP <665> Section 2, Scope, "A drug substance may be stored frozen as a solid in a container at some point in the manufacturing process, raising the question as to whether the container is within the scope of this chapter. The frozen drug substance can be stored for periods of months or longer and also for shorter periods during which the drug substance in the container is a liquid (e.g., initial filling of the container before freezing and thawing of the frozen drug substance prior to use). The period of time that the drug substance is frozen is not within the scope of this chapter and does not require risk assessment and testing; however, the period of time during which the drug substance is in a liquid form is within the scope of this chapter and requires risk assessment and appropriate testing." To support the most conservative extraction study approach, the GORE® LYOGUARD® Freeze-Drying Trays were subjected to a 24-hour, elevated temperature of 40 C of 50% ethanol with constant agitation to promote solvent contact of the entire inner surface area while maintaining the prescribed USP <665> extraction ratio of 6 cm^2/mL.

Sincerely,

Shannon Levy

Shannon Levy
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PB14244-R2-TEC-US-NOV26

EXECUTIVE SUMMARY

RE: Extractable Report for GORE® LYOGUARD® Freeze-Drying Tray

W. L. Gore & Associates, Inc. ("Gore") is providing the above-referenced report for the purpose of supplying high-quality and useful extractables data and information to end-users of the GORE® LYOGUARD® Freeze-Drying Tray. The report documents an extractables study based on guidance provided in United States Pharmacopeia and National Formulary <665> "Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products". The testing outlined in the report was performed on the Product fluid path. The study involved testing two replicates of two lots of material assembled at Gore's Elk Mills 2 site, located at 402 Vieve's Way, Elkton, Maryland, 21921 (USA). Element Materials Technology Bend, LLC ("Element") of Bend, Oregon, 97701 (USA), an independent contract laboratory, conducted the study. Element is recognized as a leader in supporting extractables testing based on extractables guidance.

This study included extractions under the following conditions:

- One (1) extraction solvent: 50% ethanol / 50% water
- One (1) exposure time: 24 hours
- One (1) exposure temperature: 40 ± 5 °C
- Extraction ratio: 6 cm^2/ml
- Constant rocking during the extraction at 80 RPM

The following analytical methods, techniques, and reporting thresholds were included in the study:

- Headspace gas chromatography with mass spectrometry and flame ionization detection (Headspace GC-MS/FID) for volatiles
  - Reporting thresholds: 0.1 µg/mL
- Gas chromatography with mass spectrometry and flame ionization detection (GC-MS/FID) for volatiles and semi-volatiles
  - Reporting thresholds: 0.1 µg/mL
- Liquid chromatography with UV and mass spectrometry detection (LC/MS) for semi-volatile and nonvolatiles
  - Reporting thresholds: 0.1 µg/mL
- Inductively coupled plasma with mass spectrometry (ICP/MS) for elemental analysis
  - Reporting limits 2-100 µg/L (element dependent)
- Semi-quantitative analysis using surrogate standards
- All semi-quantitative concentrations were calculated using response factors generated from surrogate standards.

Organic and inorganic extractables results are presented by sorting from high to low concentration. All concentration values across the replicates of materials tested are reported.

Summary Extractables Statement

Study Completion Date: June 2025

Test article	**GORE® LYOGUARD® Freeze-Drying Tray**		
Number of test articles	1 per Lot		
Part number	LGT2000		
Lot Numbers	B23801678116, B23801674910		
Pretreatment[a]	**Variable(s)**	**Units**	**Value(s)**
Gamma irradiation	Dose	kGy	N/A
Autoclave	Time, Temperature, Number of Cycles	Minutes, °C, #	N/A
Pre-flush	N/A	Name, minutes, °C, L	N/A
Test Article Extraction Conditions	**Variable**	**Units**	**Value(s)**
	Temperature	°C	40 ± 5 °C
	Duration with constant rocking @ 80 RPM	Minutes, hours, days	24 Hours
	Solvent contact surface area (9)	cm^2	2290.7 cm^2
	Solvent volume	mL	380 mL
	Surface area to volume ratio	ratio	6.0 cm^2/mL
Supporting information			
Bags	Film Thickness	mm	N/A
	Volume (capacity)	L	N/A
Tubing	Wall Thickness	inches	N/A
	Internal Diameter	inches	N/A
	Length	feet	N/A
Tubing connectors and aseptic connectors	Internal Diameter	mm	N/A
	Length	mm	N/A
Filters and TFF cassettes	EFA	m^3	N/A
Filling needles	Internal Diameter	mm	N/A
2D and 3D bags	Time between film manufacturing and gamma irradiation	Days (Lot1)	N/A
		Days (Lot2)	N/A
		Days (Lot3)	N/A
Small Parts	Extracted Part Total Surface Area	cm^2	N/A
	Fluid Contact Surface Area	cm^2	N/A
All gamma-irradiated components	Time between gamma irradiation & extraction	days	N/A
	Typical dose range during normal manufacturing	kGy	N/A
All autoclaved components	Time between autoclave & extraction (<24 hours recommended)	hours	N/A

a. If none, indicate N/A (not applicable)

USP 665 Organic Extractables (GC/MS & LC/MS)

GORE® LYOGUARD® Freeze-Drying Tray

Gore Part number: LGT2000
Lot Numbers: B23801678116, B23801674910

Study Completion Date: June 2025

Compound	CAS	Retention Time, min	24 Hours, Rep 1, µg/mL	24 Hours, Rep 2, µg/mL	Identification Classification	Extraction Solvent	Analytical Technique
1,6,11,16,21,26,31-Heptaoxacyclopentatriacontane (35-Crown-7)	66055-34-3	20.04	1.0	1.3	Confident	50% EtOH	LC/MS (ESI+)
1,6,11,16,21,26-Hexaoxacyclotriacontane (30-Crown-6)	64001-05-4	19.17	0.99	1.1	Confident	50% EtOH	LC/MS (ESI+)
Nonylphenol	84852-15-3	19.28	0.77	0.98	Confirmed	50% EtOH	LC/MS (ESI-)/UV
1,6,11,16,21,26,31,36-Octaoxacyclotetracontane (40-Crown-8)	64001-04-3	20.73	0.85	0.89	Confident	50% EtOH	LC/MS (ESI+)
1,6,11,16,21,26,31,36,41-Nonaoxacyclopentatetracontane (45 Crown-9)	66055-35-4	21.27	0.53	0.51	Confident	50% EtOH	LC/MS (ESI+)
1,6,11,16,21-Pentaoxacyclopentacosane (25-Crown-5)	56890-57-4	17.91	0.30	0.34	Confident	50% EtOH	LC/MS (ESI+)
Long chain alkyl alcohol	NA	20.69	0.30	0.30	Tentative	50% EtOH	GC/MS
Hexadecanoic acid	57-10-3	20.12	0.31	0.27	Confirmed	50% EtOH	LC/MS (ESI-)
Unknown	NA	12.67	0.23	0.23	Unknown	50% EtOH	LC/MS (ESI+)
1,6,11,16,21,26,31,36,41,46-Decaoxacyclopentacontane (50-Crown-10)	245105-93-5	21.71	0.19	0.20	Confident	50% EtOH	LC/MS (ESI+)
1,6,11,16,21,26-Hexaoxacyclotriacontane (30-Crown-6)	64001-05-4	28.60	0.18	0.20	Confident	50% EtOH	GC/MS
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- (BHT)	128-37-0	19.71	0.18	0.18	Confirmed	50% EtOH	LC/UV
Ester	NA	15.07	0.16	0.16	Tentative	50% EtOH	GC/MS
1,6,11,16,21,26,31-Heptaoxacyclopentatriacontane (35-Crown-7)	66055-34-3	32.66	0.15	0.16	Confident	50% EtOH	GC/MS
Phenol, 2,6-bis(1,1-dimethylethyl)-4-methyl- (BHT)	128-37-0	14.54	0.16	0.15	Confident	50% EtOH	GC/MS
Unknown	NA	19.74	0.089	0.13	Unknown	50% EtOH	LC/MS (ESI-)
Phenol, 4-decyl-2,6-bis (1,1-dimethylethyl)-	57511-45-2	22.18	0.11	0.12	Confident	50% EtOH	LC/MS (ESI-)
Octadecanoic acid	57-11-4	20.94	0.093	0.078	Confirmed	50% EtOH	LC/MS (ESI-)

All results semiquantitative
NA = Not Applicable

GORE CONFIDENTIAL INFORMATION

USP 665 Inorganic Extractables (ICP/MS)

GORE® LYOGUARD® Freeze-Drying Tray

Gore Part number: LGT2000
Lot Numbers: B23801678116, B23801674910

Study Completion Date: June 2025

Trace Element	CAS	Reporting Limit, µg/L	Test Control, µg/L	Lot 1, µg/L	Lot 2, µg/L	Extraction Solvent	Analytical Technique
Lithium	7439-93-2	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Magnesium	7439-95-4	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Aluminum	7429-90-5	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Vanadium	7440-62-2	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Chromium	7440-47-3	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Manganese	7439-96-5	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Iron	7439-89-6	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Cobalt	7440-48-4	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Nickel	7440-02-0	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Copper	7440-50-8	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Zinc	7440-66-6	100	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Arsenic	7440-38-2	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Molybdenum	7439-98-7	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Cadmium	7440-43-9	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Tin	7440-31-5	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Antimony	7440-36-0	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Barium	7440-39-3	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Mercury	7439-97-6	2	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS
Lead	7439-92-1	20	< Reporting Limit	< Reporting Limit	< Reporting Limit	50% Ethanol	ICP/MS

All results semiquantitative