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Gore PharmBIO Products

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May 2026

To Whom It May Concern:

RE: Extractable Report for GORE® STA-PURE® Pump Tubing, Series PCS

The attached report is an extractables study performed on GORE® STA-PURE® Pump Tubing, Series PCS ("the Product"). Test conditions were based on selected guidelines put forth by BioPhorum as stated in their Extractables Testing of Polymeric Single-Use Components Used in Biopharmaceutical Manufacturing (April 2020). This study also conforms to the guidelines of USP <665> Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceuticals Drug Substances and Products. The test results are a point in time, and do not represent a claim for each future production lot.

The product is manufactured and packaged in a clean environment 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.

Sincerely,



Keith Fritsky
Product Specialist
W. L. Gore & Associates, Inc.

Gore PharmBIO Products

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EXECUTIVE SUMMARY

RE: Extractable Report for GORE® STA-PURE® Pump Tubing, Series PCS

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 GORE® STA-PURE® Pump Tubing, Series PCS.

The study involved testing of the Product manufactured at Gore’s Elk Mills 2 site, located at 402 Vieve’s Way, Elkton, Maryland, 21921 (USA). The study was conducted by Element Materials Technology Bend, LLC (“Element”) of Bend, Oregon, 97701 (USA), an independent contract laboratory. Element is recognized as a leader in supporting extractables testing based on BioPhorum guidance. The testing outlined in the report was performed on the Product immersed in extraction solvents. This study included extractions under the following conditions:

- Four (4) extraction solvents: 50% ethanol in water, 0.5 M sodium hydroxide (NaOH), 0.1 M phosphoric acid (H_3PO_4) and Deionized (DI) water.
- Two (2) exposure times: 24 hours and 21 days at 40° C.

The following organic screening and targeted elemental 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 performed on all solvent extracts.
  - Target Reporting Thresholds: 0.10 µg/mL (0.017 µg/cm^2).
- Gas chromatography with mass spectrometry and flame ionization detection (GC/MS/FID) for volatiles and semi-volatiles performed on all solvent extracts.
  - Target Reporting Thresholds: 0.10 µg/mL (0.017 µg/cm^2).
- Liquid chromatography with ultraviolet and mass spectrometry detection (LC/UV/MS) for semi-volatile and non-volatiles performed on all solvent extracts.
  - Target Reporting Thresholds: 0.10 µg/mL (0.017 µg/cm^2).
- Inductively Coupled Plasma/Mass Spectrometry (ICP/MS) for elements in the 0.1 M phosphoric acid (H_3PO_4) extract.
  - Reporting thresholds: 0.0033 µg/cm^2 (except for Platinum and Mercury at 0.00033 µg/cm^2).

The organic extractable screening results are estimated, semi-quantitative values that used response factors generated from surrogate standards.

Based on BioPhorum guidance, organic extractables results are sorted to present a trend from high to low concentration, with identification classifications being consistent with guidance provided in USP <1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems.

This study conforms to the guidelines of USP <665> Plastic Components and Systems Used to Manufacture Pharmaceutical Drug Products and Biopharmaceuticals Drug Substances and Products.

Although there are procedural differences between the BioPhorum and USP <665> extractables protocols, BioPhorum conditions followed in this study are considered more aggressive and include augmented parameters.

- Extraction Duration: USP <665> requires a single time point for 21 days at 40°C, whereas this study employed two time points for 1 and 21 days at 40°C. The BioPhorum one-day time point will capture additional potential volatile components that may be lost over the 21-day extraction.
- Extraction Solvents: Based on a high level risk evaluation, USP <665> requires three solvents including 50% Ethanol, pH 3 water and pH 10 water. This study employed four solvents based on a high risk level assessment, including 50% Ethanol, 0.1 M phosphoric acid in water, 0.5 M sodium hydroxide in water and water for injection (WFI). The BioPhorum 0.1 M phosphoric acid solution has a pH of approximately 1.6 and is therefore more acidic than the pH 3 water. The lower BioPhorum pH is more aggressive for solubilizing metals and will not negatively impact the materials of construction. The BioPhorum 0.5 M sodium hydroxide solution has a pH of approximately 13.5 and is therefore more caustic than a pH 10 water. Some process conditions experienced by GORE® STA-PURE® Pump Tubing, Series PCS may be above a pH of 10, and materials of construction will not degrade at pH 13.5. Both solvent substitutions are permissible per USP <665>.
- Extraction Parameters: This study was performed on the Product immersed in extraction solvents. Both BioPhorum and USP <665> permit immersion extractions.
- Risk Profile Driven Testing: According to USP <1665>, low risk testing of nonvolatile residue and UV absorbance is not applicable when performing high risk organic profiling and is superseded by the speciated organic profiling employed in this study using GC/MS and LC/MS techniques.

Summary Extractables Statement

Test Article	GORE® STA-PURE® Pump Tubing Series PCS		
Number of test articles	2		
W.L. Gore Part number	ZB14ME		
W.L. Gore Lot numbers	B23801714926, B23801714872		
Pretreatment	**Variable(s)**	**Units**	**Value(s)**
Gamma irradiation	Dose	kGy	N/A
Autoclave	Time, Temperature, Number of Cycles	Minutes, °C, #	30 min, 121°C, 1 Cycle
Pre-flush	Fluid identity, duration, temperature, volume	Name, minutes, °C, L	N/A
Test Article Extraction Conditions	**Variable**	**Units**	**Value(s)**
	Temperature	°C	40
	Duration	Minutes, hours, days	1 and 21 Days
	Solvent contact surface area	cm^2	483.93 for Organics, 509.40 for Inorganics (nominal)
	Solvent volume	mL	80 for Organics and 85 for Inorganics (nominal)
	Surface area to volume ratio	ratio	6 (nominal)
Supporting Information			
Bags	Film Thickness	mm	N/A
	Volume (capacity)	L	N/A
Tubing	Wall Thickness	mm	2.4 (nominal)
	Internal Diameter	mm	3.2 (nominal)
	Length	mm	70 (nominal)
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)	
		Days (Lot3), if applicable	
All gamma-irradiated components	Time between gamma irradiation and extraction	days	N/A
	Typical dose range during normal manufacturing	kGy	N/A
All autoclaved components	Time between autoclave and extraction (<24 hours recommended)	Hours	<24

All system suitability results for sensitivity, accuracy and precision met the BPOG guidance acceptance criteria.

Organic Extractables Table

GORE® STA-PURE® Pump Tubing Series PCS

Gore Part number: ZB14ME
Lot Number: B23801714926, B23801714872
Analysis Date: January 2026

Compound	CAS	Retention Time, min	24 Hours Extract 1, µg/cm²	24 Hours Extract 2, µg/cm²	21 Days Extract 1, µg/cm²	21 Days Extract 2, µg/cm²	Identification Classification	Extraction Solvent	Analytical Technique
Silanol, 1,1,1-trimethyl-	1066-40-6	12.09	20	19	97	89	Confirmed	0.5 M NaOH	HS GC/MS/FID
Disiloxane, 1,1,1,3,3,3-hexamethyl-	107-46-0	16.09	0.83	0.78	53	9.3	Confident	0.5 M NaOH	HS GC/MS/FID
Methanol	67-56-1	3.55	ND	ND	5.5	5.5	Confirmed	50% EtOH	HS GC/MS/FID
Silanol, 1,1,1-trimethyl-	1066-40-6	2.29	ND	ND	4.3	3.3	Confident	0.5 M NaOH	GC/MS/FID
2-Propanol	67-63-0	6.32	0.43	0.40	4.2	3.8	Confirmed	0.5 M NaOH	HS GC/MS/FID
Methanol	67-56-1	3.59	0.32	0.33	2.5	2.7	Confirmed	0.5 M NaOH	HS GC/MS/FID
Silanol, 1,1,1-trimethyl-	1066-40-6	10.93/12.14	0.53	0.55	2.3	2.5	Confirmed	50% EtOH	HS GC/MS/FID
Methanol	67-56-1	3.58	ND	ND	2.2	2.2	Confirmed	0.1 M H_3PO_4	HS GC/MS/FID
Silanol, 1,1,1-trimethyl-	1066-40-6	11.86	0.62	0.67	1.6	1.6	Confirmed	0.1 M H_3PO_4	HS GC/MS/FID
Methanol	67-56-1	3.59	0.33	0.38	1.4	1.5	Confirmed	DI Water	HS GC/MS/FID
Silanol, 1,1,1-trimethyl-	1066-40-6	11.86	0.37	0.45	1.2	1.3	Confirmed	DI Water	HS GC/MS/FID
2-Propanol	67-63-0	6.88	ND	ND	0.83	0.78	Confirmed	50% EtOH	HS GC/MS/FID
Silane, trimethyl(1-methylethoxy)-	1825-64-5	2.66	ND	ND	0.72	0.33	Confident	0.5 M NaOH	GC/MS/FID
2-Propanol	67-63-0	6.35	0.12	0.11	0.67	0.50	Confirmed	0.1 M H_3PO_4	HS GC/MS/FID
2-Propanol	67-63-0	6.34	0.092	0.11	0.52	0.43	Confirmed	DI Water	HS GC/MS/FID
Silane, diethoxydimethyl-	78-62-6	1.10	0.018	0.058	0.20	0.23	Confident	DI Water	LC/MS/UV
Acetaldehyde	75-07-0	3.31	0.022	0.018	0.17	0.22	Confirmed	50% EtOH	HS GC/MS/FID
Ethane, 1,1-diethoxy-	105-57-7	26.15	ND	ND	0.15	0.18	Confirmed	50% EtOH	HS GC/MS/FID
Siloxane	NA	16.82	ND	ND	0.12	0.10	Tentative	0.5 M NaOH	LC/MS/UV
Unknown	NA	34.26	ND	ND	0.10	0.090	Unknown	0.5 M NaOH	HS GC/MS/FID
Hexanoic Acid, 2-ethyl-	149-57-5	9.82	ND	ND	0.088	ND	Confirmed	DI Water	LC/MS/UV
3-Ethoxy-1,1,3-trimethyldisiloxan-1-ol	NA	8.36	ND	ND	0.087	0.088	Confident	0.5 M NaOH	LC/MS/UV
Acetaldehyde	75-07-0	3.31	ND	ND	0.075	0.078	Confirmed	0.5 M NaOH	HS GC/MS/FID
Hexanoic acid, 2-ethyl-	149-57-5	9.03	ND	ND	0.062	ND	Confident	DI Water	GC/MS/FID
Hexadecanoic acid	57-10-3	19.94	0.040	0.048	0.060	0.065	Confident	50% EtOH	LC/MS/UV

Organic Extractables Table

GORE® STA-PURE® Pump Tubing Series PCS

Gore Part number: ZB14ME
Lot Number: B23801714926, B23801714872
Analysis Date: January 2026

Compound	CAS	Retention Time, min	24 Hours Extract 1, µg/cm²	24 Hours Extract 2, µg/cm²	21 Days Extract 1, µg/cm²	21 Days Extract 2, µg/cm²	Identification Classification	Extraction Solvent	Analytical Technique
Methoxytrimethyl-silane	1825-61-2	7.44	ND	ND	0.060	0.055	Confident	0.5 M NaOH	HS GC/MS/FID
Acetaldehyde	75-07-0	3.31	ND	ND	0.055	0.058	Confirmed	0.1 M H_3PO_4	HS GC/MS/FID
Unknown	NA	3.96	ND	ND	0.055	0.037	Unknown	0.5 M NaOH	GC/MS/FID
1-Hexanol, 2-ethyl-	104-76-7	37.58	0.038	0.038	0.053	0.070	Confirmed	0.5 M NaOH	HS GC/MS/FID
13-Docosenamide, (13Z)- (Erucamide)	112-84-5	21.88	0.055	0.053	0.053	0.043	Confident	50% EtOH	LC/MS/UV
Acetic acid, 2-ethylhexyl ester	103-09-3	9.42	0.043	0.052	0.052	0.055	Confident	50% EtOH	GC/MS/FID
Siloxane	NA	5.98	0.047	0.067	0.047	0.017	Tentative	DI Water	LC/MS/UV
1-Hexanol, 2-ethyl-	104-76-7	37.57	0.043	0.047	0.042	0.045	Confirmed	0.1 M H_3PO_4	HS GC/MS/FID
Unknown	NA	10.72	0.033	0.037	0.040	0.040	Unknown	50% EtOH	GC/MS/FID
Hexadecanoic acid	57-10-3	19.81	ND	ND	0.038	0.062	Confirmed	0.5 M NaOH	LC/MS/UV
1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester	84-74-2	19.24	ND	ND	0.038	0.037	Confident	0.5 M NaOH	GC/MS/FID
Hexadecanoic acid	57-10-3	19.24	ND	ND	0.038	0.037	Confident	0.5 M NaOH	GC/MS/FID
Unknown	NA	11.09	0.018	0.018	0.038	0.022	Unknown	50% EtOH	LC/MS/UV
Silanol, 1,1,1-trimethyl-	1066-40-6	2.48	ND	ND	0.033	0.020	Confident	50% EtOH	GC/MS/FID
Silane, diethoxydimethyl-	78-62-6	3.66	ND	ND	0.030	0.030	Confident	50% EtOH	GC/MS/FID
Siloxane	NA	19.87	0.027	0.023	0.028	0.025	Tentative	50% EtOH	LC/MS/UV
2-Propanone	67-64-1	5.90	ND	ND	0.027	ND	Confirmed	DI Water	HS GC/MS/FID
1-Hexanol, 2-ethyl-	104-76-7	37.57	0.032	0.040	0.025	0.037	Confirmed	DI Water	HS GC/MS/FID
Silanol, 1,1,1-trimethyl-	1066-40-6	2.25	ND	ND	0.025	0.028	Confident	DI Water	GC/MS/FID
Ethanol, 2-(2-butoxyethoxy)-	112-34-5	10.05	0.057	0.060	0.023	0.027	Confident	50% EtOH	LC/MS/UV
Ethanol, 2-(2-ethoxyethoxy)-	111-90-0	7.16	ND	0.043	0.023	0.018	Confident	0.5 M NaOH	GC/MS/FID
Ethanol, 2-(2-butoxyethoxy)-	112-34-5	10.07	0.078	0.063	0.022	0.022	Confident	0.1 M H_3PO_4	LC/MS/UV
1,5-Dioxacycloundecane-6,11-dione, 3,3-dimethyl-	94113-47-0	12.44	0.042	0.080	0.020	0.032	Confident	50% EtOH	LC/MS/UV
Ethanol, 2-(2-ethoxyethoxy)-	111-90-0	7.16	0.040	0.052	0.020	0.023	Confident	DI Water	GC/MS/FID
Unknown	NA	15.15	ND	ND	0.020	0.020	Unknown	50% EtOH	LC/MS/UV

Organic Extractables Table

GORE® STA-PURE® Pump Tubing Series PCS

Gore Part number: ZB14ME
Lot Number: B23801714926, B23801714872
Analysis Date: January 2026

Compound	CAS	Retention Time, min	24 Hours Extract 1, µg/cm²	24 Hours Extract 2, µg/cm²	21 Days Extract 1, µg/cm²	21 Days Extract 2, µg/cm²	Identification Classification	Extraction Solvent	Analytical Technique
2-Propanone	67-64-1	5.92	ND	ND	0.020	0.018	Confirmed	0.5 M NaOH	HS GC/MS/FID
≥C8 Benzoyl	NA	0.56	ND	ND	0.020	0.018	Tentative	50% EtOH	LC/MS/UV
1,5-Trisiloxanediol, 1,1,3,3,5,5-hexamethyl-	3663-50-1	15.09	ND	ND	0.020	0.014	Confident	50% EtOH	LC/MS/UV
1-Oxaspiro[4.5] deca-6,9-diene-2, 8-dione, 7,9-bis(1,1-dimethylethyl)-	82304-66-3	17.23	0.028	0.035	0.017	0.042	Confident	50% EtOH	LC/MS/UV
Octadecanoic acid	57-11-4	20.77	0.0088	0.013	0.015	0.017	Confident	50% EtOH	LC/MS/UV
2H-Azepin-2-one, hexahydro-(Caprolactam)	105-60-2	4.77	ND	ND	0.014	0.025	Confirmed	DI Water	LC/MS/UV
Ethanol, 2-(2-ethoxyethoxy)-	111-90-0	4.65	0.020	0.023	0.010	0.013	Confident	0.1 M H_3PO_4	LC/MS/UV
Unknown	NA	10.43	ND	ND	ND	0.028	Unknown	DI Water	GC/MS/FID
1,5-Dioxacycloundecane-6,11-dione,3,3-dimethyl-	94113-47-0	14.82	ND	0.022	ND	0.022	Confident	50% EtOH	GC/MS/FID
9,12-Octadecadienoic acid (9Z,12Z)-	60-33-3	20.88	ND	ND	ND	0.020	Confident	50% EtOH	GC/MS/FID
Ethanol, 2-(2-ethoxyethoxy)-	111-90-0	7.15	ND	0.020	ND	0.018	Confident	0.1 M H_3PO_4	GC/MS/FID
Unknown	NA	22.79	ND	ND	ND	0.017	Unknown	50% EtOH	GC/MS/FID
Ethanol, 2-(2-butoxyethoxy)-	112-34-5	10.06	0.043	0.042	ND	0.010	Confident	DI Water	LC/MS/UV
C4 Polyethoxylated alcohols (Mw 382-646)	NA	19.00	ND	0.022	ND	0.030	Tentative	50% EtOH	LC/MS/UV
Ethanol, 2-(2-ethoxyethoxy)-	111-90-0	7.38	0.038	0.042	ND	ND	Confident	50% EtOH	GC/MS/FID
1-Hexanol, 2-ethyl-	104-76-7	8.29	0.022	0.017	ND	ND	Confident	50% EtOH	GC/MS/FID
Unknown	NA	14.36	0.043	0.060	ND	ND	Unknown	50% EtOH	GC/MS/FID
Ethanol, 2-(2-butoxyethoxy)-	112-34-5	10.01	0.032	0.032	ND	ND	Confident	DI Water	GC/MS/FID
Unknown	NA	15.34	0.015	0.017	ND	ND	Unknown	50% EtOH	LC/MS/UV
Unknown	NA	17.26	0.018	0.015	ND	ND	Unknown	50% EtOH	LC/MS/UV
Ethanol, 2-(2-ethoxyethoxy)-	111-90-0	4.62	0.014	0.027	ND	ND	Confident	DI Water	LC/MS/UV
1,5-Dioxacycloundecane-6,11-dione,3,3-dimethyl-	94113-47-0	12.46	0.0060	0.020	ND	ND	Confident	DI Water	LC/MS/UV

Inorganic Extractables Table

GORE® STA-PURE® Pump Tubing Series PCS

Gore Part number: ZB14ME
Lot Number: B23801714926, B23801714872
Analysis Date: January 2026

Element	CAS	Reporting Limit, µg/cm²	Test Control, µg/cm²	Extract 1, µg/cm²	Extract 2, µg/cm²	Extraction Solvent	Analytical Technique
Silicon	7440-21-3	0.0033	2.0	2.0	2.0	0.1 M H_3PO_4	ICP/MS
Iron	7439-89-6	0.0033	< Reporting Limit	0.0054	0.0051	0.1 M H_3PO_4	ICP/MS
Zinc	7440-66-6	0.0033	< Reporting Limit	0.0037	0.0050	0.1 M H_3PO_4	ICP/MS
Aluminum	7429-90-5	0.0033	< Reporting Limit	0.0042	0.0039	0.1 M H_3PO_4	ICP/MS
Magnesium	7439-95-4	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Platinum	7440-06-4	0.00033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Lithium	7439-93-2	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Vanadium	7440-62-2	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Chromium	7440-47-3	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Manganese	7439-96-5	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Cobalt	7440-48-4	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Nickel	7440-02-0	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Copper	7440-50-8	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Arsenic	7440-38-2	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Molybdenum	7439-98-7	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Cadmium	7440-43-9	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Tin	7440-31-5	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Antimony	7440-36-0	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Barium	7440-39-3	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Mercury	7439-97-6	0.00033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS
Lead	7439-92-1	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1 M H_3PO_4	ICP/MS

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