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Together, improving life

February 2026

To Whom It May Concern:

RE: Extractables Report for GORE® STA-PURE® SU PRO™ Transfer Pump Tubing (Post X-Ray Radiation)

The attached report is an extractables study performed on GORE® STA-PURE® SU PRO™ Transfer Pump Tubing, ("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.

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PBI4322-R2-TEC-US-NOV26

EXECUTIVE SUMMARY

RE: Extractables Report for GORE® STA-PURE® SU PRO™ Transfer Pump Tubing (Post X-Ray Radiation)

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® SU RPO™ Transfer Pump Tubing.

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, 0.5M sodium hydroxide (NaOH), 0.1M 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 0.1M 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® SU PRO™ Transfer Pump Tubing 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® SU PRO™ Transfer Pump Tubing**		
Number of test articles	2		
W. L. Gore Part number	ZB14RC		
W. L. Gore Lot numbers	RD62914, RD62915 (OR6553)		
Pretreatment	**Variable(s)**	**Units**	**Value(s)**
X-Ray Irradiation	Dose	kGy	48.0 - 50.7 (September 23, 2025)
Autoclave	Time, Temperature, Number of Cycles	Minutes, °C, #	N/A
Pre-flush	Fluid identity, duration, temperature, volume	Name, minutes, °C, L	N/A
Test Article Extraction Conditions	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 x-ray irradiated components	Time between x-ray irradiation and extraction	Weeks	< 8
	Typical dose range during normal manufacturing	kGy	N/A
All autoclaved components	Time between autoclave and extraction (<24 hours recommended)	Hours	N/A

Organic Extractables Table

GORE® STA-PURE® SU PRO™ Transfer Pump Tubing (Post X-Ray Radiation)

Gore Part number: ZB14RC
Lot Number: RD62914, RD62915 (OR6553)

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	23	24	90	89	Confirmed	0.5M NaOH	GC/MS/FID
Disiloxane, 1,1,1,3,3,3-hexamethyl-	107-46-0	16.07	0.95	1.1	26	19	Confident	0.5M NaOH	GC/MS/FID
Methanol	67-56-1	3.56	3.0	3.8	11	11	Confirmed	50% EtOH	GC/MS/FID
Acetaldehyde	75-07-0	3.31	0.22	0.23	7.5	6.2	Confirmed	50% EtOH	GC/MS/FID
Ethane, 1,1-diethoxy-	105-57-7	26.11	ND	ND	5.5	4.5	Confirmed	50% EtOH	GC/MS/FID
Methanol	67-56-1	3.57	2.0	2.0	5.0	4.8	Confirmed	0.1M H_3PO_4	GC/MS/FID
Methanol	67-56-1	3.58	1.6	2.2	4.7	4.5	Confirmed	0.5M NaOH	GC/MS/FID
2-Propanol	67-63-0	6.31	0.73	0.78	4.3	4.0	Confirmed	0.5M NaOH	GC/MS/FID
Silanol, 1,1,1-trimethyl-	1066-40-6	10.92/12.13	0.68	0.67	4.2	4.0	Confirmed	50% EtOH	GC/MS/FID
Methanol	67-56-1	3.59	1.3	1.1	3.2	3.5	Confirmed	DI Water	GC/MS/FID
Silanol, 1,1,1-trimethyl-	1066-40-6	11.86	1.0	0.92	2.3	2.3	Confirmed	0.1M H_3PO_4	GC/MS/FID
Silanol, 1,1,1-trimethyl-	1066-40-6	11.87	0.45	0.33	1.5	1.7	Confirmed	DI Water	GC/MS/FID
2-Propanol	67-63-0	6.87	ND	ND	1.2	1.0	Confirmed	50% EtOH	GC/MS/FID
2-Propanol	67-63-0	6.32	0.62	0.53	1.1	1.1	Confirmed	0.1M H_3PO_4	GC/MS/FID
Silanol, 1,1,1-trimethyl-	1066-40-6	2.27	1.3	1.4	0.95	1.1	Confident	0.5M NaOH	GC/MS/FID
2-Propanol	67-63-0	6.33	0.35	0.25	0.65	0.73	Confirmed	DI Water	GC/MS/FID
Acetaldehyde	75-07-0	3.30	0.11	0.11	0.43	0.43	Confirmed	0.1M H_3PO_4	GC/MS/FID
Acetaldehyde	75-07-0	3.31	0.13	0.12	0.33	0.37	Confirmed	DI Water	GC/MS/FID
Ethane, 1,1-diethoxy-	105-57-7	3.34	ND	ND	0.27	0.33	Confident	50% EtOH	GC/MS/FID
Unknown	Unknown	34.26	ND	ND	0.20	0.18	Unknown	0.5M NaOH	GC/MS/FID
Disiloxane, 1,1,1,3,3,3-hexamethyl-	107-46-0	16.07	ND	ND	0.14	0.16	Confident	0.1M H_3PO_4	GC/MS/FID
Acetic acid	64-19-7	2.53	0.037	0.12	0.14	0.043	Confident	50% EtOH	GC/MS/FID
3-Ethoxy-1,1,3-trimethyldisiloxan-1-ol	NA	8.37	ND	ND	0.11	0.12	Confident	0.5M NaOH	LC/MS/UV
Siloxane	NA	16.83	ND	ND	0.11	0.12	Tentative	0.5M NaOH	LC/MS/UV
Silane, diethoxydimethyl-	78-62-6	3.68	ND	ND	0.11	0.16	Confident	50% EtOH	GC/MS/FID
Methoxytrimethylsilane	1825-61-2	7.43	ND	ND	0.10	0.10	Confident	0.5M NaOH	GC/MS/FID
Silanol, 1,1,1-trimethyl-	1066-40-6	2.58	ND	0.020	0.082	0.038	Confident	50% EtOH	GC/MS/FID
2-Propanone	67-64-1	5.90	0.038	0.038	0.070	0.068	Confirmed	0.1M H_3PO_4	GC/MS/FID
Unknown	NA	16.93	ND	ND	0.068	0.060	Unknown	50% EtOH	GC/MS/FID

Organic Extractables Table

GORE® STA-PURE® SU PRO™ Transfer Pump Tubing (Post X-Ray Radiation)

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
Cyclopentasiloxane-2,6-diol, 2,4,4,6,8,8,10,10-octamethyl-	86637-13-0	18.43	0.032	0.035	0.067	0.052	Confident	50% EtOH	LC/MS/UV
Siloxane	NA	19.87	0.047	0.042	0.060	0.048	Tentative	50% EtOH	LC/MS/UV
Butanoic acid	107-92-6	4.11	ND	0.020	0.053	0.070	Confident	50% EtOH	GC/MS/FID
Unknown	NA	4.11	ND	0.020	0.053	0.070	Unknown	50% EtOH	GC/MS/FID
2-Propanone	67-64-1	5.89	0.037	ND	0.053	0.057	Confirmed	DI Water	GC/MS/FID
Octadecanoic acid	57-11-4	20.77	0.030	0.023	0.053	0.057	Confirmed	50% EtOH	LC/MS/UV
Hexadecanoic acid	57-10-3	19.94	0.027	0.020	0.050	0.050	Confirmed	50% EtOH	LC/MS/UV
Hexadecanoic acid	57-10-3	19.76	ND	ND	0.050	0.035	Confirmed	0.5M NaOH	LC/MS/UV
Cyclotetrasiloxane-2,6-diol, 2,4,4,6,8,8-hexamethyl-	18134-87-7	16.72	0.020	0.025	0.043	0.037	Confident	50% EtOH	LC/MS/UV
Unknown	NA	2.66	ND	ND	0.035	0.045	Unknown	50% EtOH	GC/MS/FID
Ethane, 1,1'-[methylenebis(oxy)] bis-	462-95-3	2.91	ND	0.052	0.032	ND	Confident	50% EtOH	GC/MS/FID
≥C8 Benzoyl a	NA	0.55	ND	ND	0.032	0.038	Tentative	50% EtOH	LC/MS/UV
Silane, fluorotrimethyl-	420-56-4	3.42	ND	ND	0.032	0.028	Confident	0.1M H_3PO_4	GC/MS/FID
Silane, trimethyl(1-methylethoxy)-	1825-64-5	2.65	0.16	0.15	0.030	0.032	Confident	0.5M NaOH	GC/MS/FID
Pentanoic acid	109-52-4	5.43	ND	0.018	0.030	0.030	Confident	50% EtOH	GC/MS/FID
Unknown	NA	8.67	0.022	0.025	0.030	0.028	Unknown	50% EtOH	GC/MS/FID
Octadecanoic acid	57-11-4	21.12	ND	ND	0.027	0.030	Confident	0.5M NaOH	GC/MS/FID
Silanol, 1,1,1-trimethyl-	1066-40-6	2.25	ND	ND	0.025	0.018	Confident	0.1M H_3PO_4	GC/MS/FID
1-(1-Ethoxyethoxy)-propane	20680-10-8	3.99	ND	ND	0.023	ND	Confident	50% EtOH	GC/MS/FID
1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester	84-74-2	19.24	ND	ND	0.023	0.037	Confident	0.5M NaOH	GC/MS/FID
Hexadecanoic acid	57-10-3	19.24	ND	ND	0.023	0.037	Confident	0.5M NaOH	GC/MS/FID
Unknown	NA	17.17	0.020	0.020	0.023	0.020	Unknown	50% EtOH	LC/MS/UV
2-Propanone	67-64-1	5.90	0.023	0.020	0.022	0.025	Confirmed	0.5M NaOH	GC/MS/FID
Cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-	556-67-2	6.88	ND	0.018	0.022	0.020	Confident	50% EtOH	GC/MS/FID
Hexanoic acid	142-62-1	6.88	ND	0.018	0.022	0.020	Confident	50% EtOH	GC/MS/FID
Unknown	NA	15.19	0.020	0.020	0.022	0.020	Unknown	50% EtOH	LC/MS/UV

Organic Extractables Table

GORE® STA-PURE® SU PRO™ Transfer Pump Tubing (Post X-Ray Radiation)

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
Butanedioic acid, monoethyl ester	1070-34-4	9.72	ND	ND	0.020	0.023	Confident	50% EtOH	GC/MS/FID
Propanal	123-38-6	5.65	ND	ND	0.020	0.020	Confirmed	0.1M H_3PO_4	GC/MS/FID
3,5,7,9,11-Pentaoxa-2,4,6,8,10,12-hexasilatridecan-2-ol, 2,4,4,6,6,8,8,10,10,12-decamethyl-	139958-56-8	20.75	0.016	0.012	0.020	0.020	Confident	50% EtOH	LC/MS/UV
Unknown	Unknown	36.91	ND	ND	0.020	0.018	Unknown	0.5M NaOH	GC/MS/FID
Propanoic acid	79-09-4	3.11	ND	0.017	0.020	0.017	Confident	50% EtOH	GC/MS/FID
Unknown	NA	10.74	ND	ND	0.018	ND	Unknown	50% EtOH	GC/MS/FID
Unknown	NA	11.45	0.020	0.018	0.018	0.020	Unknown	50% EtOH	LC/MS/UV
Unknown	NA	18.87	0.025	0.025	0.018	0.015	Unknown	50% EtOH	LC/MS/UV
Unknown	NA	11.14	ND	ND	0.017	0.020	Unknown	50% EtOH	GC/MS/FID
Hexanoic acid	142-62-1	6.85	ND	ND	0.017	0.020	Confident	0.5M NaOH	GC/MS/FID
Cyclotetrasiloxane-2,2-diol, 4,4,6,6,8,8-hexamethyl-	352469-76-2	15.91	ND	ND	0.017	0.011	Confident	50% EtOH	LC/MS/UV
Unknown	NA	19.38	ND	ND	0.017	0.0040	Unknown	50% EtOH	LC/MS/UV
Unknown	NA	0.49	ND	ND	0.015	0.014	Unknown	50% EtOH	LC/MS/UV
Unknown	NA	15.50	0.017	0.016	0.015	0.018	Unknown	50% EtOH	LC/MS/UV
Unknown	NA	12.13	0.012	0.014	0.015	0.016	Unknown	50% EtOH	LC/MS/UV
Unknown	NA	17.74	ND	ND	0.015	0.0038	Unknown	50% EtOH	LC/MS/UV
Cyclopentasiloxane-2,2-diol, 4,4,6,6,8,8,10,10-octamethyl-	352469-87-5	18.04	0.020	0.015	0.010	0.0082	Confident	50% EtOH	LC/MS/UV
Benzenesulfonic acid, 4-undecyl-	39156-49-5	18.10	ND	ND	0.0088	0.014	Confident	50% EtOH	LC/MS/UV
Benzenesulfonic acid, 4-dodecyl-	121-65-3	18.63	ND	ND	0.0068	0.0075	Confident	50% EtOH	LC/MS/UV
Benzoic acid	65-85-0	1.27	ND	ND	0.0067	0.0080	Confirmed	DI Water	LC/MS/UV
Nonanoic acid	112-05-0	11.15	ND	ND	ND	0.018	Confident	0.5M NaOH	GC/MS/FID
Octanoic acid	124-07-2	9.77	ND	ND	ND	0.017	Confident	0.5M NaOH	GC/MS/FID
Acetaldehyde	75-07-0	3.30	0.020	ND	ND	ND	Confirmed	0.5M NaOH	GC/MS/FID
Unknown	NA	3.21	ND	0.018	ND	ND	Unknown	50% EtOH	GC/MS/FID
Unknown	NA	3.41	ND	0.038	ND	ND	Unknown	50% EtOH	GC/MS/FID

Inorganic Extractables Table

GORE® STA-PURE® SU PRO™ Transfer Pump Tubing (Post X-Ray Radiation)

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	2.9	2.9	0.1M H_3PO_4	ICP/MS
Iron	7439-89-6	0.0033	< Reporting Limit	0.0060	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Zinc	7440-66-6	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Aluminum	7429-90-5	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Magnesium	7439-95-4	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Platinum	7440-06-4	0.00033	< Reporting Limit	0.0012	0.0012	0.1M H_3PO_4	ICP/MS
Lithium	7439-93-2	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Vanadium	7440-62-2	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Chromium	7440-47-3	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Manganese	7439-96-5	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Cobalt	7440-48-4	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Nickel	7440-02-0	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Copper	7440-50-8	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Arsenic	7440-38-2	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Molybdenum	7439-98-7	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Cadmium	7440-43-9	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Tin	7440-31-5	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Antimony	7440-36-0	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Barium	7440-39-3	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Mercury	7439-97-6	0.00033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS
Lead	7439-92-1	0.0033	< Reporting Limit	< Reporting Limit	< Reporting Limit	0.1M H_3PO_4	ICP/MS