

VALIDATION GUIDE

GENDERLESS SERIESLOCK Xgen® CONNECTOR

SeriesLock
Xgen™

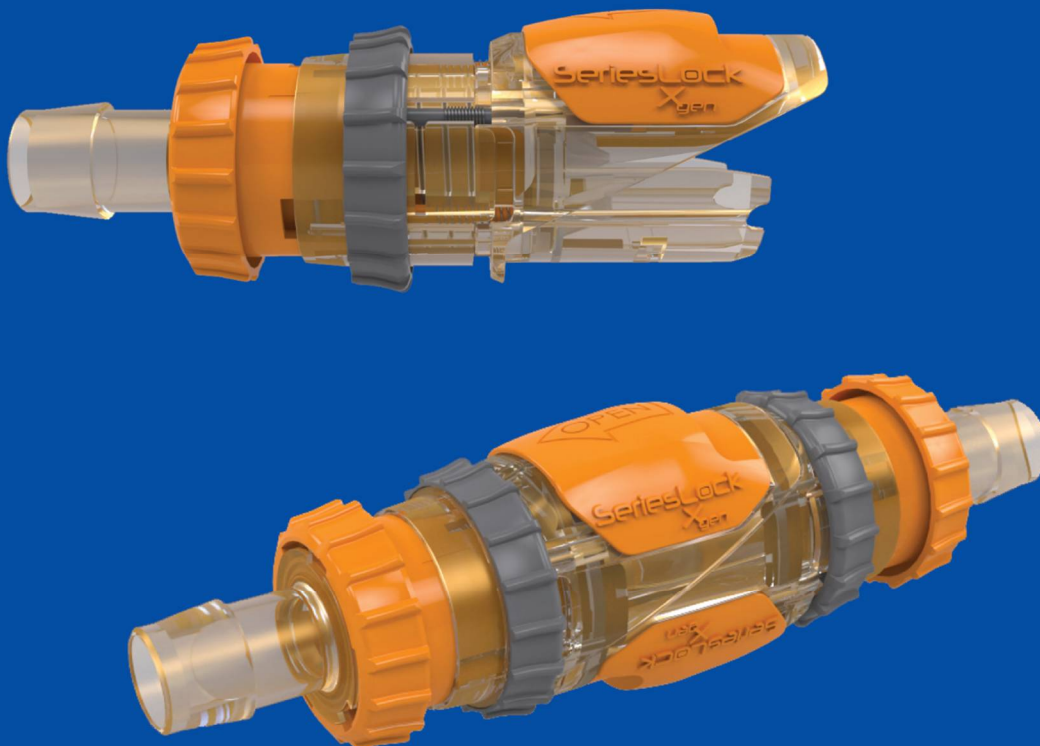


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1.0 VALIDATION OVERVIEW

1.1 Introduction

The purpose of this validation guide is to document the regulatory compliance and testing results of the genderless SeriesLock Xgen® connector. Compliance and testing results contained within detail applicable material attributes (mechanical, material, regulatory, etc.) in order to provide users with the information necessary to assess the suitability of these products for use.

This content of this document, which is based on supplier declarations and our own material knowledge and testing, is intended to be used for informational purposes only; it is provided free of charge, without prejudice, and should not be viewed as giving technical advice, instruction, or otherwise. Use of this information is intended for persons with the requisite technical expertise and regulatory knowledge, who will make their own determination as to its suitability, prior to use and at their own discretion and risk. Eldon James makes no warranty or representation as to the completeness or accuracy of the information contained herein.

Prior to the specification of a product, evaluation of materials under end-use conditions is essential, as those factors (pressure, temperature, other environmental substances, etc.) may affect the performance of the product. Ultimately, it is the customer's responsibility to determine that use of this product is safe, lawful, and technically suitable for the intended application.

1.2 Scope

The SeriesLock Xgen product line is widely used in bioprocessing and medical device applications; they are manufactured according to GMP standards, meet USP Class VI requirements, and all materials are animal derivative free. Genderless SeriesLock Xgen products are manufactured in compliance with ISO 9001:2015 and ISO 13485:2016 standards and are controlled and inspected in accordance with applicable product specifications and standard operating procedures.

1.3 Effective Date

The information contained within this document is current as of January 8th, 2026.

1.4 Product Manufacturer and Country of Origin

SeriesLock Xgen is manufactured in the U.S.A. by the Eldon James Corporation:
3420 Precision Drive, Fort Collins, CO 80528

1.5 Manufacturing Environment

Genderless SeriesLock Xgen products are manufactured in an ISO 14644 Class 7 cleanroom environment; in a facility certified to ISO 9001:2015 and ISO 13485:2016 standards.

1.6 Shelf Life, Storage Conditions, and Expiration Date

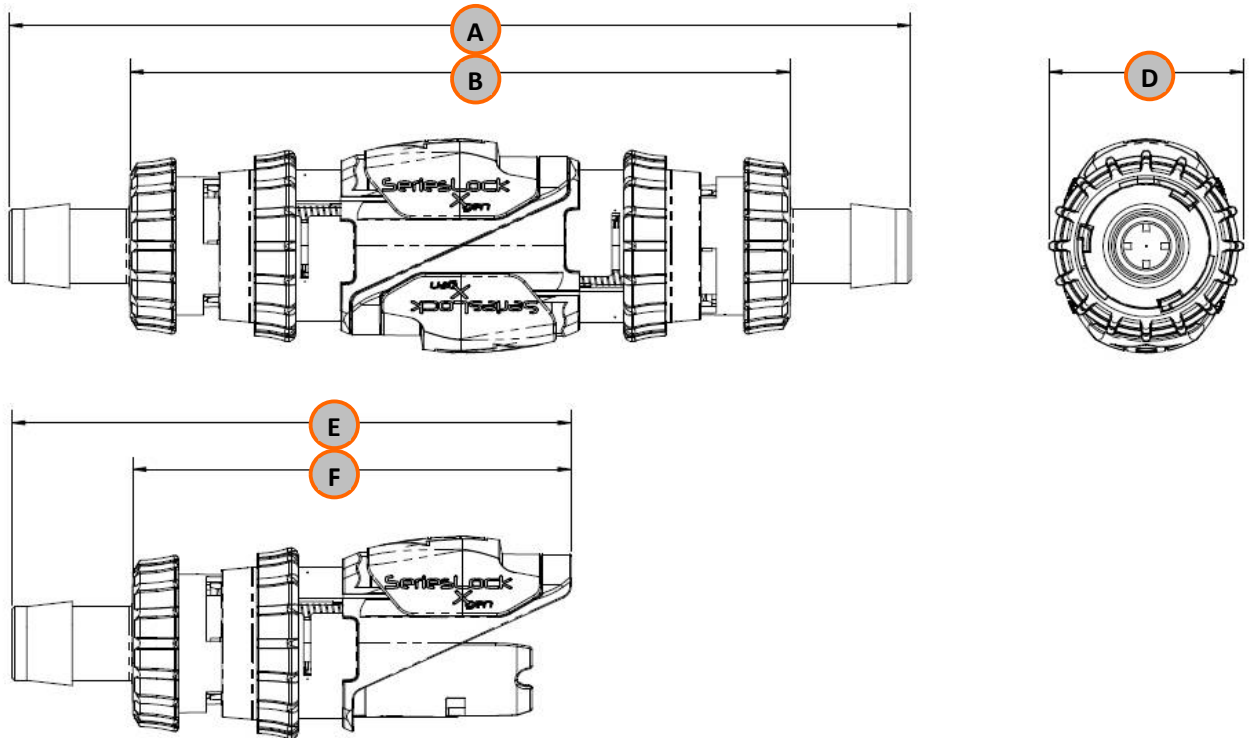
Eldon James does not publish a shelf life on this product; however, raw materials are stored for a relatively short time before use. Additionally, these products should be stored in dry conditions, at room temperatures, and out of direct sunlight or other sources of UV radiation. Improper storage conditions can initiate premature degradation of color, odor, and physical properties.

As these products may be used in many different applications and conditions, Eldon James does not make any assessments or claims regarding product expiration. Each individual application should be tested by the customer to determine the limits of each product, material, and use.

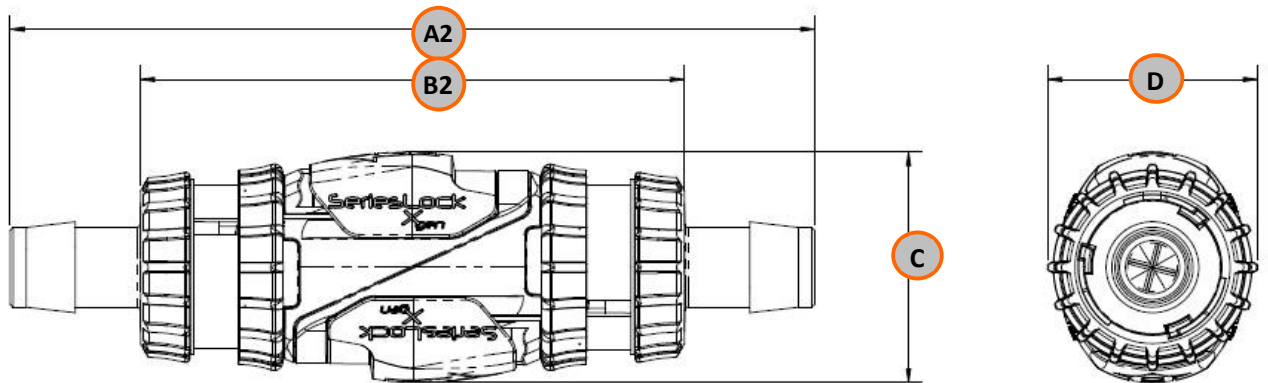


2.0 DIMENSIONS AND WEIGHTS

2.1 Left-to-Right Connected (Valves NOT OPEN)



2.2 Left-to-Right Connected (Valves OPEN)



Tubing Size	Barb Fittings (Dimensions in Inches)							
	A	B	A2	B2	C	D	E	F
1/4"	8.06	6.58	6.51	5.03	2.17	1.94	5.11	4.37
3/8"	8.26		6.71				5.21	
1/2"	8.58		7.03				5.37	
3/4"	8.98		7.43				5.57	
1"	9.38		7.83				5.77	



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2.3 Internal Surface Area and Volumes

Tubing Size	Surface Area (cm ²)	Volume (cc)	HOLD-UP Volume ⁽¹⁾ (cc)
1/4"	35.40	8.88	0.002
3/8"	37.43	9.49	
1/2"	40.30	10.57	
3/4"	44.97	14.93	
1"	56.45	20.94	

⁽¹⁾Maximum possible captive volume inside flow path per half per nominal 3D models.

2.4 Cv Values

Tubing Size	Flow (GPM)
3/8"	1.01
1/2"	1.765
3/4"	2.375
1"	2.394

2.5 Weights (grams) – One Half Only, Polysulfone Housings

Tubing Size	PS
1/4"	87
3/8"	87
1/2"	88
3/4"	90
1"	94

3.0 MATERIALS OF CONSTRUCTION

Full Technical Datasheets available upon request.

3.1 Udel P-1700 NT 11 (Polysulfone Housing)

Attribute	Nominal Value (English/SI)	Test Method
Specific Gravity	1.24 g/cm ³	ASTM D792
Tensile Strength (yield)	10193 psi/70.3 MPa	ASTM D638
Tensile Elongation (break)	50 to 100%	ASTM D638
Notched Izod Impact (73°F, 23°C)	1.29 ft-lb/in69 J/m	ASTM D256
Deflection Temperature Under Load (264psi-1.82 MPa unannealed)	345°F / 174°C	ASTM D648
Melt Temperature	330°C to 385°C 625°F to 725°F	–
Flame Rating	–	–
1.5 mm	HB	UL 94
4.5 mm	V-0	UL 94



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3.2 Platinum Cured Silicone (Seals)

Attribute	Nominal Value (English / SI)	Test Method
Tensile Strength	1340 psi	ASTM D412
Tensile Modulus	530 psi	ASTM D638
Elongation	580%	ASTM D412
Heat Deflection Temperature	219.2°F (104°C)	ASTM D256
High Tear Yes	Yes	ASTM D790
Operating Temperature High	450°F	-
Operating Temperature Low	-80°F	-
Hardness, Shore A	D74	D2240

3.3 Solvay Radel R-5000 (Polyphenylsulfone Button/Latch)

Attribute	Nominal Value (English/SI)	Test Method
Specific Gravity	1.29 g/cm3	ASTM D792
Tensile Strength (yield)	10100 psi / 69.6 MPa	ASTM D638
Tensile Elongation (break)	60 to 120%	ASTM D638
Notched Izod Impact (73°F, 23°F)	13 ft-lb/in / 690 J/m	ASTM D256
Deflection Temperature Under Load (264psi-1.82 MPa unannealed)	405°F / 207°C	ASTM D648
Melt Temperature	360°C to 391°C 680°F to 735°F	-
Flame Rating - .030 in / 0.76mm	V-0	UL 94

3.4 PFPE Lubrication

Some Xgen assemblies are manufactured with a biocompatible medical grade lubricant.

Attribute	Nominal Value (English / SI)	Test Method
Estimated Use Range	-36°C to 204°C (-33°F to 400°F)	-
Oil Viscosity, cSt		
20°C (65°F)	522	-
40°C (104°F)	160	-
100°C (212°F)	18	-
204°C (400°F)	3.1	-
Oil Pour Point	-36°C, -33°F	-
Oil Density, g/ml		
0°C (32°F)	1.94	-
100°C (212°F)	1.76	-
Maximum Oil Volatility (% in 22 hr.)		
121°C (250°F)	1	ASTM D2595
204°C (400°F)	7	ASTM D2595



4.0 PHYSICAL SPECIFICATIONS

4.1 Pressure Rating

- 30 psi / 2.07 bar

4.2 Temperature Range

- Service Temperature -20°F to 300°F (-62°C to 149°C)
- Storage Temperature -80°F to 300°F (-62°C to 149°C)

4.3 Safety Lockout-Ring Rating

- Resists up to 8 lbf

5.0 STERILIZATION METHODS⁽¹⁾

	Gamma	E-Beam	X-Ray	ETO	Autoclave	
					121°C	134°C
SeriesLock Xgen®	Yes	Yes	Yes ⁽²⁾	Yes	Yes	Yes

⁽¹⁾ End user to verify sterilization cycle based on the use environment and sterilization mode chosen.

⁽²⁾ Xgen has not been tested using X-ray sterilization, however, all material vendor information states compatibility should not be an issue.

5.1 Irradiation

Typical radiation cycle <50 kGy

5.2 Autoclave

- 121°C for 30 minutes (unwrapped) followed by 15-30 minutes drying time.
- 134°C for 45 minutes (unwrapped) followed by 15-30 minutes drying time.

6.0 REGULATORY COMPLIANCE

6.1 Animal Derivatives & Transmissible Spongiform Encephalitis (TSE/BSE) Risk

Based on the information available from our raw material suppliers; these materials do not intentionally contain substances from animal derivatives.

6.2 CA Prop 65 (Safe Drinking Water and Toxic Enforcement Act of 1986)

Udel P-1700 NT 11: This product can expose you to chemicals including Bisphenol A (CAS # 80-05-7), which is/are known to the State of California to cause birth defects or other reproductive harm.

Platinum Cured Silicone: This material does contain specific types of phthalates which are known to the State of California to cause cancer, birth defects, and other reproductive harm.



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6.3 Conflict Materials (Dodd-Frank Wall Street Reform & Consumer Protection Act)

Per our raw material suppliers, this product is not intentionally manufactured or formulated with the listed conflict minerals as per Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act: Columbite-Tantalite – refined into Tantalum (Ta) (CAS # 7440-25-7), Cassiterite – refined into Tin (Sn) (CAS # 7440-31-5), Wolframite – refined into Tungsten (W) (Cas # 7440-33-7), and Gold AU (Cas # 7440-57-5)

6.4 Food Contact Status

Udel P-1700 NT 11: Complies with FDA 21 CFD 177.1655 and may be used in articles intended for repeated contact with foods. Additionally, they are approved by the NSF, by the Department of Agriculture for contact with meat and poultry and by the 3-A Sanitary Standards of the Dairy Association

Platinum Cured Silicone: Complies with FDA 21 CFD 177-2600 Rubber articles intended for repeated use may be safely used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

6.5 Genetically Modified Organisms (GMOs)

Udel P-1700 NT 11: Based on available information these products do not intentionally contain any materials from genetically modified organisms.

6.6 Heavy Metals – Coalition of Northeastern Governors (CONEG)

Udel P-1700 NT 11: Cadmium, hexavalent chromium, lead, and mercury have not been intentionally added or used during the manufacturing process.

Platinum Cured Silicone: Based on information from the supplier this product does not intentionally contain any materials classified as heavy metals.

6.7 Per- and Polyfluoroalkyl Substances (PFAS)

Udel P-1700 NT 11: Based on the information provided to us by our raw material supplier, Per- and Polyfluoroalkyl Substances are not intentionally added or used in the manufacturing process of this product. However, the absence of these substances has not been verified by testing.

PFPE Lubrication: No Per- and Polyfluoroalkyl Substances were detected as the result of material testing (per EPA US Environmental Protection Agency protocols using LC/MS/MS and Solid=Phase Extraction).

6.8 Plant Derived Constituents

Udel P-1700 NT 11: Plant derived constituents are not intentionally used in the formulation or manufacture of this product and are therefore not expected to be present. The absence of these substances has not been verified by testing.

6.9 RoHS 3 – Restriction of Hazardous Substances (EU Directive 2015/863/EU)

Udel P-1700 NT 11 and PFPE Lubrication: This product does not contain as intentional ingredients any of the ten restricted chemicals above their threshold limits per the EU Directive 2015/863-ROHS amending Annex II to EU ROHS 2 (Directive 2011/65/EU: Lead, Cadmium, Mercury, Hexavalent chromium, Polybrominated biphenyls (PBBs), Polybrominated diphenyl ethers (PBDEs), Bis(2-ethylhexyl) phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP), and Diisobutyl phthalate (DIBP)



6.10 REACH Substances of Very High Concern (SVHC)

Udel P-1700 NT 11: Based on the information provided to us from our raw material supplier and their formulation reviews, they confirm that this product does not contain SVHC Candidate List Annex XIV materials above the applicable threshold (0.1%) as updated by the European Chemical Agency as of June 25th, 2025 (250 substances).

PFPE Lubrication: Based on information provided from the raw material supplier, this product does not contain above 0.1% any SVHC substances as of November 7th, 2024 (242 Substances).

6.11 Substances (additional)

Udel P-1700 NT 11: The following substances are not used in the formulation or manufacturing of this product:

- Melamine
- Natural Rubber Latex
- Nitrosamines
- Phthalates

PFPE Lubrication: Nitrosamines are not used in the formulation or manufacturing of this product.

6.12 Toxic Substances Control Act (TSCA) Inventory

Udel P-1700 NT 11: Based on information provided to us from our raw material supplier, this product is not intentionally formulated or manufactured with the five PBT (persistent, bio-accumulative, and reprotoxic) substances as listed in TSCA section 6(h) (per the U.S. Environmental Protection Agency’s (EPA) published final rules restricting the importation and use PBT chemicals).

7.0 TESTING

7.1 Flow Rate Testing

Objective:

Flow rate testing was conducted to obtain Cv values for the SeriesLock Xgen® product family.

Methodology:

A baseline flow rate was obtained using common tubing in place of Xgen assemblies of similar barb size to tube ID. After verification of equipment and test setup, a “Y” valve was gradually adjusted to eliminate cavitation and stabilize flow; the “Y” valve then remained fixed for the duration of testing to ensure data consistency. Once system stability was achieved, two pressure gauges were activated and an upstream valve was adjusted to reach a 1 psi differential. Stabilized pressure and flow rate readings were then recorded for each tubing baseline. The testing procedure documented above was then repeated with Xgen assemblies of each barb size / tubing ID; flow rate readings were recorded for each.

Results:

BASELINE FLOW RATE				Xgen FLOW RATE			
Tubing Size	Flow (GPM)	Inlet Pressure	Outlet Pressure	Xgen Barb Size	Flow (GPM)	Inlet Pressure	Outlet Pressure
FLXC 6-10	1.39	1.600	0.600	0.38”	1.01	1.400	0.400
FLXC 8-12	2.93	1.800	0.800	0.50”	1.765	1.520	0.520
FLXC 12-16	7.58	3.400	2.400	0.75”	2.375	1.630	0.630
FLXC 16-20	8.43	3.800	2.800	1.00”	2.394	1.620	0.620



7.2 Aerosol Testing

Aerosolized bacteria testing was conducted on the SeriesLock Xgen genderless connector to assess its resistance to bacterial contamination through repeated connect / disconnect / reconnect (CDR) cycles.

Objective:

To evaluate the connector’s resistance to bacterial ingress using *Brevundimonas diminuta*, a common environmental bacterium and potential opportunistic pathogen.

Methodology:

- Preparation: All equipment and samples were sterilized via autoclave prior to testing. Testing assemblies were constructed from disconnected Xgen® components, Flexelene™ 135C tubing, and a peristaltic pumps. These assemblies were then aseptically filled with sterile tryptic soy broth. In addition, a challenge media was prepared with *B. diminuta* at a concentration of 2 x 10⁸ CFU/ml.
- Aerosol Challenge: The inner septum of each connector was exposed to the aerosolized challenge media (approx. 0.3ml – 0.5ml at the concentration noted above) and allowed to dry for 5 minutes. The halves were then connected, completing the circuit, and allowed to flow for 10 minutes.
- Testing Cycles: Component pairs underwent repeated CDR cycles with periodic microbial exposure, sample collection, and analysis.
- Sample Collection and Analysis: During each disconnection cycle, 100µl of tryptic soy broth was collected from the flow path, spread evenly on tryptic soy agar plates, and incubated at 30°C for 72hours. After incubation the plates were analyzed for the presence of microbial growth.
- Controls: positive and negative controls were used to verify the integrity of the bacterial challenge and ensure no background microbial contamination.

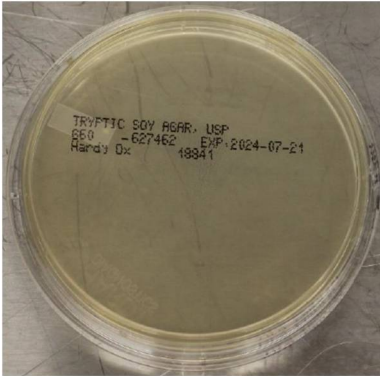


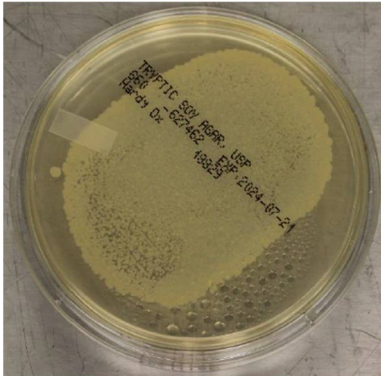
Results:

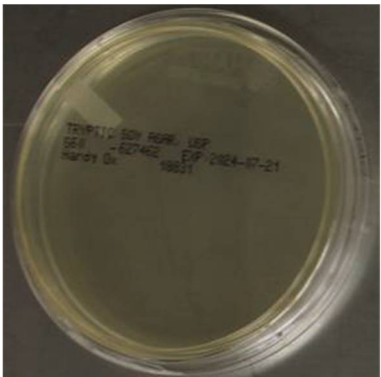



The Xgen connector maintained a sterile fluid path through the specified CDR cycles (see tables below). Testing was conducted with a built-in safety factor, validating performance beyond the specified limit to ensure reliability and robust contamination resistance.

	Cycle	# Colony Forming Units (CFU)	Concentration (Cells/ml)
Phase I	1	0.00	< 1.00 CFU/ml
	2	0.00	< 1.00 CFU/ml
	3	0.00	< 1.00 CFU/ml
	4	0.00	< 1.00 CFU/ml
	5	0.00	< 1.00 CFU/ml
	10	0.00	< 1.00 CFU/ml

	Cycle	# Colony Forming Units (CFU)	Concentration (Cells/ml)
Phase II	1	0.00	< 1.00 CFU/ml
	2	0.00	< 1.00 CFU/ml
	3	0.00	< 1.00 CFU/ml
	4	0.00	< 1.00 CFU/ml
	5	0.00	< 1.00 CFU/ml
	10	0.00	< 1.00 CFU/ml




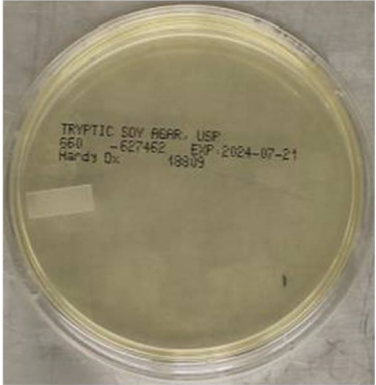

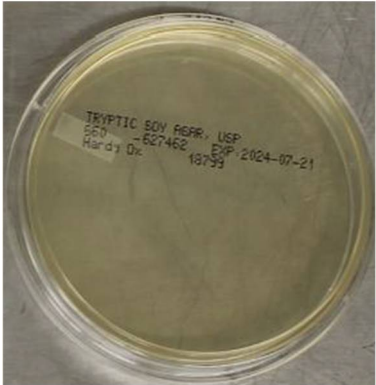

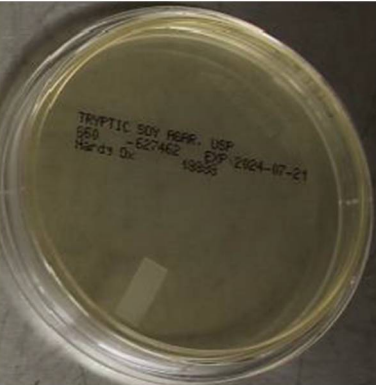


	Phase I	Phase II
Growth results for sterile broth (negative control)		
Growth results for bacterial challenge (positive control)		

	Phase I	Phase II
Bacterial Aerosol Challenge Test Results – Cycle 1		
Bacterial Aerosol Challenge Test Results – Cycle 2		



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	Phase I	Phase II
Bacterial Aerosol Challenge Test Results – Cycle 3	 <p>TRYPTIC SOY BEARR. USP 560 -E27462 EXP:2024-07-21 Hardy Dc 19911</p>	 <p>TRYPTIC SOY BEARR. USP 560 -E27462 EXP:2024-07-21 Hardy Dc 19909</p>
Bacterial Aerosol Challenge Test Results – Cycle 4	 <p>TRYPTIC SOY BEARR. USP 560 -E27462 EXP:2024-07-21 Hardy Dc 19911</p>	 <p>TRYPTIC SOY BEARR. USP 560 -E27462 EXP:2024-07-21 Hardy Dc 19799</p>
Bacterial Aerosol Challenge Test Results – Cycle 5	 <p>TRYPTIC SOY BEARR. USP 560 -E27462 EXP:2024-07-21 Hardy Dc 19992</p>	 <p>TRYPTIC SOY BEARR. USP 560 -E27462 EXP:2024-07-21 Hardy Dc 19995</p>
Bacterial Aerosol Challenge Test Results – Cycle 10	 <p>TRYPTIC SOY BEARR. USP 560 -E27462 EXP:2024-07-21 Hardy Dc 19972</p>	 <p>TRYPTIC SOY BEARR. USP 560 -E27462 EXP:2024-07-21 Hardy Dc 19975</p>



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Conclusion:

The SeriesLock Xgen® connector successfully resisted bacterial ingress up to the specified limit, with testing demonstrating a margin of safety beyond this range. This report supports confirmation of contamination resistance; nevertheless, regulatory approvals remain the responsibility of the customer/end-user.

7.3 Particulate Testing – USP <788>

Objective:

The purpose of this test is to quantify the count and size of subvisible particles in parenteral drugs. Particle sizes ≥10 µm and ≥25 µm are the focus.

Methodology:

A beaker was triple rinsed with Mili-Q water. 1000mL of Water-for-Injection was added to the beaker along with an Xgen sample device; the device was submerged. The beaker was covered, placed on an orbital shaker for one hour, then allowed to degas for 2 minutes before sampling. Sampling was performed using a Lighthouse liquid sampler system.

Results:

Volume	UOM	≥ 10 µm		≥ 25 µm	
		USP 788 Particle Limits	Xgen Test Results	USP 788 Particle Limits	Xgen Test Results
> 100mL	particles/mL	25	1.3	3	0.1
≤ 100 mL	particles/container	6000	1	600	< 1

7.4 Biocompatibility Testing

7.4.1 Udel® P-1700 NT 11

The following ISO 10993 testing has been completed for Udel® P-1700 NT 11. All samples were steam sterilized prior to testing, with the exception of pyrogen testing samples which were gamma sterilized (2 runs at target dose of 25kGy).

- ISO 10993-4:2002 (Hemolysis)

Test Description: Hemolysis, in vitro with sodium chloride extract (121°C/1 hrs)

Result/Comments: Test article extract was nonhemolytic with a mean hemolytic index of 0%

- ISO 10993-5:2009 (Cytotoxicity)

Test Description: Cytotoxicity using the ISO elution method (37°C/24 hrs)

Result/Comments: No evidence of causing cell lysis or toxicity



- ISO 10993-10:2002 (Irritation / Sensitization)
 - Test Description: Maximum Sensitization with sodium chloride extract (121°C/1 hr)
 - Result/Comments: No evidence of causing delayed dermal contact sensitization
 - Test Description: Maximum Sensitization with sesame oil extract (121°C/1 hr)
 - Result/Comments: No evidence of causing delayed dermal contact sensitization

- ISO 10993-10:2002 (Intracutaneous Reactivity)
 - Test Description: Intracutaneous Reactivity with sodium chloride extract (121°C/1 hr)
 - Result/Comments: No erythema and no edema from the extract injected intracutaneously. The primary irritation index characterization for the extracts was negligible.
 - Test Description: Intracutaneous Reactivity with sesame oil extract (121°C/1 hr)
 - Result/Comments: Very slight erythema and no edema from the intracutaneously injected extract. The primary irritation index characterization for the extracts was negligible.

- ISO 10993-11:1993 (Systemic Toxicity)
 - Test Description: USP & ISO Systemic Toxicity Study with sodium chloride extract (121°C/1 hr)
 - Result / Comments: No mortality or evidence of systemic toxicity from the extracts.
 - Test Description: USP & ISO Systemic Toxicity Study with sesame oil extract (121°C/1 hr)
 - Result / Comments: No mortality or evidence of systemic toxicity from the extracts.

- USP General Chapter <151> (Pyrogen Test)
 - Test Description: USP Material Mediated Pyrogen (70°C/24 hrs)
 - Result / Comments: The test article extract was judged as non-pyrogenic.

7.4.2 PFPE Lubrication

Physical, chemical, and toxicological testing was performed per ISO 10993 and/or USP Class VI standards.

Test Description: ANSI / AAMI / ISO 10993-10:2010 / (R) 2014 – Dermal Sensitization study.

Result / Comments: The test article is a non-sensitizer according to the conditions of the study

7.5 Extractable / Leachable Testing – Udel P-1700 NT 11

Extractable Leachable testing was performed on the Udel P-1700 NT 11 Polysulfone by the raw material manufacturer. This testing was conducted using BPOG/BPSA guidance on evaluation for Leachables and Extractables for Single-Use Systems in Biomanufacturing. Prior to testing, samples were gamma sterilized at 50 kGy. Results of this testing are listed on pages 16 – 19.



Test Article	Pellets			
# of Test Articles	~10 Grams pellets			
Sample ID	Udel P1700 NT Lot # P170331			
Solvent System	Deionized Water			
Pretreatment	Gamma Irradiation	kGy	50 +/- 5	
Leachable Test Conditions (Temperature 25°C, Duration 30 minutes)	Variable(s)	Unit(s)	Value(s)	LoQ
	Temperature	Celcius	25	
	Duration	Minutes	30	
	Solvent contact surface area	cm2	174	
	Solvent volume	mL	29	
	Surface are to volume ratio	cm2/mL (SA/V)	6:1	
	Extraction (orbital shaker)	rpm	70	
	GC-MS testing	ppb	Non Detect	420 [in sample] (Butylated hydroxytoluene)
	GC-FID testing	ppb	Non Detect	820 (Biphenyl), 510 (BHT) 865 (average) [in sample]
	UPLC-PDA	ppb	Non Detect	200 (Irganox 1010)
	UPLC-MS (ESI +)	ppb	Non Detect	53 (Irganox 1010)
	UPLC-MS (ESI -)	ppb	Non Detect	110 (Irganox 245)
	UPLC-MS (APCI+)	ppb	Non Detect	22 (Irganox 1098)
	UPLC-MS (APCI-)	ppm	Non Detect	14 (Irganox 245)
Extractable Test Conditions (Temperature 40°C, Duration 24 hours)	Variable(s)	Unit(s)	Value(s)	
	Temperature	Celcius	40	
	Duration	Hours	24	
	Solvent contact surface area	cm2	174	
	Solvent volume	mL	29	
	Surface are to volume ratio	cm2/mL (SA/V)	6:1	
	Extraction (orbital shaker)	rpm	70	
	GC-MS testing	ppb	Non Detect	420 [in sample] (Butylated hydroxytoluene)
	GC-FID testing	ppb	Non Detect	820 (Biphenyl), 510 (BHT) 865 (average) [in sample]
	UPLC-PDA	ppb	Non Detect	200 (Irganox 1010)
	UPLC-MS (ESI +)	ppb	Non Detect	53 (Irganox 1010)
	UPLC-MS (ESI -)	ppb	Non Detect	110 (Irganox 245)
	UPLC-MS (APCI+)	ppb	Non Detect	22 (Irganox 1098)
	UPLC-MS (APCI-)	ppm	Non Detect	14 (Irganox 245)
Extractable Test Conditions (Temperature 40°C, Duration 168 hours)	Variable(s)	Unit(s)	Value(s)	
	Temperature	Celcius	40	
	Duration	Hours	168	
	Solvent contact surface area	cm2	174	
	Solvent volume	mL	29	
	Surface are to volume ratio	cm2/mL (SA/V)	6:1	
	Extraction (orbital shaker)	rpm	70	
	GC-MS testing	ppb	Non Detect	420 [in sample] (Butylated hydroxytoluene)
	GC-FID testing	ppb	Non Detect	820 (Biphenyl), 510 (BHT) 865 (average) [in sample]
	UPLC-PDA	ppb	Non Detect	200 (Irganox 1010)
	UPLC-MS (ESI +)	ppb	Non Detect	53 (Irganox 1010)
	UPLC-MS (ESI -)	ppb	Non Detect	110 (Irganox 245)
	UPLC-MS (APCI+)	ppb	Non Detect	22 (Irganox 1098)
	UPLC-MS (APCI-)	ppm	Non Detect	14 (Irganox 245)
Supporting Information				
Analytical equipment: GC-FID=Agilent 8890N or 7890, GC-MS=Agilent 8890N/5973MSD equipped with an Electron Impact Ionization, UPLC-PDA=Waters Aquity with PDA, UPLC-MS (ESI+, ESI-, APCI+, APCI-) = Waters Synapt G2 HDM5				
Extraction system: Thermo Scientific Max Q-420 HP				
Water: ASTM Type I water from a Millipore Integral 3				
[in sample]=Analytical Method Dilution Factor Applied				
Spike and recovery was between 99-105% for 1 ppm of BPA				



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Test Article	Pellets					
# of Test Articles	~10 Grams pellets					
Sample ID	Udel P1700 NT Lot # P170331					
Solvent System	Deionized Water					
Pretreatment	Gamma Irradiation	kGy	50 +/- 5			
Exposure Conditions	Temperature: 25°C	Temperature: 40°C	Temperature: 40°C	ICP Limit of Detection / Quantification		
	30 minutes	24 hours	1 week	LOD:	LOQ (Water):	
Element	(ppm)	(ppm)	(ppm)	(ppm)	(ppm)	
Al	Non Detect	Non Detect	Non Detect	0.0112	0.04	
Sb	Non Detect	Non Detect	Non Detect	0.0047	0.02	
As	Non Detect	Non Detect	Non Detect	0.0104	0.03	
Ba	Non Detect	Non Detect	Non Detect	0.0068	0.02	
Be	Non Detect	Non Detect	Non Detect	0.0071	0.02	
Bi	Non Detect	Non Detect	Non Detect	0.0071	0.02	
B	0.20	0.04	0.12	0.0050	0.02	
Cd	Non Detect	Non Detect	Non Detect	0.0052	0.02	
Ca	Non Detect	Non Detect	0.07	0.0111	0.04	
Cr	Non Detect	Non Detect	Non Detect	0.0091	0.03	
Co	Non Detect	Non Detect	Non Detect	0.0035	0.01	
Cu	Non Detect	Non Detect	Non Detect	0.0080	0.03	
Ga	Non Detect	Non Detect	Non Detect	0.0054	0.02	
Ge	Non Detect	Non Detect	Non Detect	0.0027	0.01	
Au	Non Detect	Non Detect	Non Detect	0.0079	0.03	
Hf	Non Detect	Non Detect	Non Detect	0.0053	0.02	
In	Non Detect	Non Detect	Non Detect	0.0070	0.02	
Ir	Non Detect	0.13	Non Detect	0.0037	0.01	
Fe	Non Detect	0.06	0.09	0.0108	0.04	
Pb	Non Detect	Non Detect	Non Detect	0.0050	0.02	
Li	Non Detect	Non Detect	Non Detect	0.0077	0.03	
Mg	Non Detect	Non Detect	Non Detect	0.0077	0.03	
Mn	Non Detect	Non Detect	Non Detect	0.0075	0.03	
Mo	Non Detect	Non Detect	Non Detect	0.0029	0.01	
Ni	Non Detect	Non Detect	Non Detect	0.0075	0.03	
Nb	Non Detect	Non Detect	Non Detect	0.0045	0.01	
Pd	Non Detect	Non Detect	Non Detect	0.0050	0.02	
P	Non Detect	Non Detect	Non Detect	0.0064	0.02	
Pt	Non Detect	Non Detect	Non Detect	0.0066	0.02	
K	Non Detect	0.03	0.02	0.0076	0.03	
Re	Non Detect	Non Detect	Non Detect	0.0026	0.01	
Rh	Non Detect	Non Detect	Non Detect	0.0044	0.01	
Ru	Non Detect	Non Detect	Non Detect	0.0066	0.02	
Se	Non Detect	Non Detect	Non Detect	0.0145	0.05	
Si	Non Detect	0.04	Non Detect	0.0112	0.04	
Ag	Non Detect	0.05	Non Detect	0.0069	0.02	
Na	0.01	Non Detect	0.27	0.0101	0.03	
Sr	Non Detect	Non Detect	Non Detect	0.0071	0.02	
Ta	Non Detect	Non Detect	Non Detect	0.0044	0.01	
Te	Non Detect	0.11	Non Detect	0.0106	0.04	
Tl	Non Detect	Non Detect	Non Detect	0.0075	0.02	
Sn	Non Detect	0.06	Non Detect	0.0068	0.02	
Ti	Non Detect	Non Detect	Non Detect	0.0026	0.01	
W	Non Detect	0.10	Non Detect	0.0032	0.01	
V	Non Detect	0.01	Non Detect	0.0078	0.03	
Zn	Non Detect	Non Detect	Non Detect	0.0088	0.03	
Zr	Non Detect	Non Detect	Non Detect	0.0034	0.01	

Supporting Information:
 Spike and recovery was between 70% to 150% (per USP <233>) when spiked at 0.33 ppm with multi-element standards for the following elements: Sb, As, Ba, Be, Bi, Cd, Cr, Co, Cu, Ga, Ge, Hf, In, Ir, Fe, Pb, Li, Mg, Mn, Mo, Ni, Nb, Pd, P, Pt, Re, Rh, Ru, Se, Ag, Sr, Te, Ti, Sn, Ti, W, V, Zn, Zr
 Spike and recovery did not fall between 70% to 150% (per USP <233>) when spiked at 0.33 ppm with multi-element standards for the following elements: Al, B, Ca, K, Si, Na (Elements from Glass Vials) or Au (156-167% recovery) or Ta (90% at 30 min, 81% at 24 hrs, 67% at 168 hrs)
 Analytical equipment: ICP=Perkin Elmer Optima 8300
 Water: ASTM Type I water from a Millipore Integral 3
 BDH ARISTAR ICP multi-element standards:
 89800-608 (contains 10 ppm: Ag, Al, As, Ba, Be, Bi, Ca, Cd, Co, Cr, Cs, Cu, Fe, Ge, In, K, Li, Mg, Mn, Na, Ni, Pb, Rb, Se, Sr, Tl, U, V and Zn) [matrix: 5% (v/v) HNO3]
 89800-622 (contains 10 ppm: Au, Hf, Ir, Pd, Pt, Rh, Ru, Sb, Sn and Te) [matrix: 1% (v/v) HNO3, 10% (v/v) HCl]
 89800-624 (contains 10 ppm: B, Ge, Mo, Nb, P, re, s, Si, ta, Ti, W and Zr) [matrix: 5% (v/v) HNO3 tr HF]



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Test Article	Pellets			
# of Test Articles	~10 Grams pellets			
Sample ID	Udel P1700 NT Lot # P170331			
Solvent System	Deionized Water / Ethanol 50:50			
Pretreatment	Gamma Irradiation	kGy	50 +/- 5	
Leachable Test Conditions (Temperature 25°C, Duration 30 minutes)	Variable(s)	Unit(s)	Value(s)	LoQ
	Temperature	Celcius	25	
	Duration	Minutes	30	
	Solvent contact surface area	cm2	174	
	Solvent volume	mL	29	
	Surface are to volume ratio	cm2/mL (SA/V)	6:1	
	Extraction (orbital shaker)	rpm	70	
	GC-MS testing	ppb	Non Detect	84 (Butylated hydroxytoluene)
	GC-FID testing	ppb	Below LoQ	164 (Biphenyl), 102 (BHT), 133 (average)
	UPLC-PDA	ppb	Non Detect	200 (Irganox 1010)
	UPLC-MS (ESI +)	ppb	Below LoQ	53 (Irganox 1010)
	UPLC-MS (ESI -)	ppb	Non Detect	110 (Irganox 245)
	UPLC-MS (APCI+)	ppb	Non Detect	22 (Irganox 1098)
	UPLC-MS (APCI-)	ppm	Non Detect	14 (Irganox 245)
Extractable Test Conditions (Temperature 40°C, Duration 24 hours)	Variable(s)	Unit(s)	Value(s)	
	Temperature	Celcius	40	
	Duration	Hours	24	
	Solvent contact surface area	cm2	174	
	Solvent volume	mL	29	
	Surface are to volume ratio	cm2/mL (SA/V)	6:1	
	Extraction (orbital shaker)	rpm	70	
	GC-MS testing	ppb	Non Detect	84 (Butylated hydroxytoluene)
	GC-FID testing	ppb	Unknown 381ppb (@4.89 minutes)	164 (Biphenyl), 102 (BHT), 133 (average)
	UPLC-PDA	ppb	Below LoQ	200 (Irganox 1010)
	UPLC-MS (ESI +)	ppb	Below LoQ	53 (Irganox 1010)
	UPLC-MS (ESI -)	ppb	Unknown 173 ppb (@5.31 minutes)	110 (Irganox 245)
	UPLC-MS (APCI+)	ppb	Non Detect	22 (Irganox 1098)
	UPLC-MS (APCI-)	ppm	Non Detect	14 (Irganox 245)
Extractable Test Conditions (Temperature 40°C, Duration 168 hours)	Variable(s)	Unit(s)	Value(s)	
	Temperature	Celcius	40	
	Duration	Hours	168	
	Solvent contact surface area	cm2	174	
	Solvent volume	mL	29	
	Surface are to volume ratio	cm2/mL (SA/V)	6:1	
	Extraction (orbital shaker)	rpm	70	
	GC-MS testing	ppb	Non Detect	84 (Butylated hydroxytoluene)
	GC-FID testing	ppb	Unknown 485ppb (@4.89 minutes)	164 (Biphenyl), 102 (BHT), 133 (average)
	UPLC-PDA	ppb	Below LoQ	200 (Irganox 1010)
	UPLC-MS (ESI +)	ppb	Below LoQ	53 (Irganox 1010)
	UPLC-MS (ESI -)	ppb	Non Detect	110 (Irganox 245)
	UPLC-MS (APCI+)	ppb	Non Detect	22 (Irganox 1098)
	UPLC-MS (APCI-)	ppm	Non Detect	14 (Irganox 245)
Supporting Information				
Analytical equipment: GC-FID=Agilent 6890N or 7890, GC-MS=Agilent 6890N/5973MSD equipped with an Electron Impact Ionization, UPLC-PDA=Waters Aquity with PDA, UPLC-MS (ESI+, ESI-, APCI+, APCI-)= Waters Synapt G2 HDMS				
Extraction system: Thermo Scientific Max Q-420 HP				



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Test Article	Pellets				
# of Test Articles	~10 Grams pellets				
Sample ID	Udel P1700 NT Lot # P170331				
Solvent System	Deionized Water / Ethanol 50:50				
Pretreatment	Gamma Irradiation		kGy	50 +/- 5	
Exposure Conditions	Temperature: 25°C	Temperature: 40°C	Temperature: 40°C	ICP Limit of Detection / Quantification	
	30 minutes	24 hours	1 week	LOD:	LOQ (Ethanol:Water)
Element	(ppm)	(ppm)	(ppm)	(ppm)	(ppm)
Al	0.27	0.17	0.12	0.0112	0.12
Sb	Non Detect	0.09	Non Detect	0.0047	0.05
As	Non Detect	0.12	0.09	0.0104	0.12
Ba	0.11	Non Detect	Non Detect	0.0068	0.08
Be	Non Detect	Non Detect	Non Detect	0.0071	0.08
Bi	Non Detect	Non Detect	Non Detect	0.0071	0.08
B	0.62	0.35	2.24	0.0050	0.06
Cd	Non Detect	Non Detect	Non Detect	0.0052	0.06
Ca	0.2	0.2	0.06	0.0111	0.12
Cr	Non Detect	Non Detect	Non Detect	0.0091	0.1
Co	Non Detect	Non Detect	Non Detect	0.0035	0.04
Cu	0.01	0.02	0.07	0.0080	0.09
Ga	Non Detect	Non Detect	Non Detect	0.0054	0.06
Ge	Non Detect	Non Detect	Non Detect	0.0027	0.03
Au	Non Detect	Non Detect	Non Detect	0.0079	0.09
Hf	Non Detect	Non Detect	Non Detect	0.0053	0.06
In	Non Detect	Non Detect	Non Detect	0.0070	0.08
Ir	0.03	0.03	0.01	0.0037	0.04
Fe	Non Detect	Non Detect	0.04	0.0108	0.12
Pb	Non Detect	Non Detect	Non Detect	0.0050	0.06
Li	Non Detect	Non Detect	Non Detect	0.0077	0.09
Mg	Non Detect	Non Detect	Non Detect	0.0077	0.09
Mn	Non Detect	Non Detect	Non Detect	0.0075	0.08
Mo	Non Detect	Non Detect	Non Detect	0.0029	0.03
Ni	Non Detect	Non Detect	Non Detect	0.0075	0.08
Nb	Non Detect	Non Detect	Non Detect	0.0045	0.05
Pd	Non Detect	Non Detect	Non Detect	0.0050	0.06
P	Non Detect	Non Detect	Non Detect	0.0064	0.07
Pt	Non Detect	Non Detect	Non Detect	0.0066	0.07
K	0.17	0.08	Non Detect	0.0076	0.08
Re	Non Detect	Non Detect	Non Detect	0.0026	0.03
Rh	Non Detect	Non Detect	Non Detect	0.0044	0.05
Ru	Non Detect	Non Detect	Non Detect	0.0066	0.07
Se	Non Detect	Non Detect	0.04	0.0145	0.16
Si	1.06	0.45	0.35	0.0112	0.12
Ag	Non Detect	Non Detect	Non Detect	0.0069	0.08
Na	1.03	0.65	3.1	0.0101	0.11
Sr	Non Detect	Non Detect	Non Detect	0.0071	0.08
Ta	Non Detect	Non Detect	Non Detect	0.0044	0.05
Te	Non Detect	0.03	0.01	0.0106	0.12
Tl	Non Detect	Non Detect	Non Detect	0.0075	0.08
Sn	Non Detect	Non Detect	0.06	0.0068	0.08
Ti	Non Detect	Non Detect	Non Detect	0.0026	0.03
W	Non Detect	Non Detect	Non Detect	0.0032	0.04
V	Non Detect	Non Detect	Non Detect	0.0078	0.09
Zn	Non Detect	0.14	Non Detect	0.0088	0.1
Zr	Non Detect	Non Detect	Non Detect	0.0034	0.04

Supporting Information:

Spike and recovery was between 70% to 150% (per USP <233>) when spiked at 0.33 ppm with multi-element standards for the following elements: Sb, As, Ba, Be, Bi, Cd, Cr, Co, Cu, Ga, Ge, Hf, In, Ir, Fe, Pb, Li, Mg, Mn, Mo, Ni, Nb, Pd, P, Pt, Re, Rh, Ru, Se, Ag, Sr, Te, Ti, Sn, Ti, W, V, Zn, Zr

Spike and recovery did not fall between 70% to 150% (per USP <233>) when spiked at 0.33 ppm with multi-element standards for the following elements: Al, B, Ca, K, Si, Na (Elements from Glass Vials) or Au (156-167% recovery) or Ta (90% at 30 min, 81% at 24 hrs, 67% at 168 hrs)

Analytical equipment: ICP=Perkin Elmer Optima 8300
 Water: ASTM Type I water from a Millipore Integral 3
 BDH ARISTAR ICP multi-element standards:
 89800-808 (contains 10 ppm: Ag, Al, As, Ba, Be, Bi, Ca, Cd, Co, Cr, Cs, Cu, Fe, Ge, In, K, Li, Mg, Mn, Na, Ni, Pb, Rb, Se, Sr, Tl, U, V and Zn) [matrix: 5% (v/v) HNO3]
 89800-822 (contains 10 ppm: Au, Hf, Ir, Pd, Pt, Rh, Ru, Sb, Sn and Te) [matrix: 1% (v/v) HNO3, 10% (v/v) HCl]
 89800-824 (contains 10 ppm: B, Ge, Mo, Nb, P, re, s, Si, ta, Ti, W and Zr) [matrix: 5% (v/v) HNO3 tr HF]



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