Citadel™ Series

All-fluoropolymer Filter Cartridges

Performance Qualification Guide

ISO 9001:2015

Preface

Each section of this Validation Guide represents only the summary portion of the actual test. If your company has a need for expanded detail on any particular test method or the actual data, please contact Graver Technologies Liquid Filter Group for assistance at 800-249-1990.

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Introduction

The Graver Technologies CITADEL™ (0.05 µm, 0.1 µm, 0.2 µm, 0.45 µm, 1.0 µm and 10 µm) pleated filter cartridges are designed as an exceptionally clean, non-leaching, non-shedding barrier for membrane filtration. These filters offer reliable performance in removing minute contaminants larger than their rated pore sizes. All CITADEL filter cartridges incorporate PTFE (polytetrafluoroethylene) membrane with fluoropolymer components (cage, core, end caps and support layers), either PFA (perfluoroalkoxy), PTFE or FEP (Fluorinated ethylene propylene). CITADEL filters are manufactured in an ISO Class 7 cleanroom environment. Each filter is rinsed with 18 megohm-cm resistivity de-ionized water to single digit TOC readings and integrity tested before release from manufacture. The Citadel filter products are fabricated in an ISO 9001, Rev. 2015 Registered manufacturing facility.

This report contains results of laboratory tests performed on Graver Technologies' CITADEL membrane cartridge filters.

Nomenclature & Construction

CITADEL NOMENCLATURE INFORMATION					
Filter Type	**Retention Rating** (microns)	**Nominal Length** (inches)	**End Configuration**	**Gasket or O-Ring**	**Option**
Citadel Series Filters	0.05 0.45 0.1 1 0.2 10	–10 –20 –30 –40	P2 226/Flat Single Open End P3 222/Flat Single Open End	C Chemraz K Kalrez T Teflon encap. Viton (Standard)	–W Pre-Wet
Example: CTL 0.05–20P3T–W					
CTL	0.05	–20	P3	T	–W

Materials of Construction

Membrane:	Single layer expanded polytetrafluoroethylene (e-PTFE) – 8.6 ft^2 (0.8 m^2)
Drainage Layer:	FEP
Core:	PFA
Cage/Outer Sleeve:	PFA
End Caps:	PFA
O-Rings:	Teflon Encapsulated Viton (standard) Chemraz® Kalrez®

Product Traceability

CITADEL Filter Elements are manufactured in conformance with established current Good Manufacturing Practice (cGMP) standards. The filter elements are produced and distributed according to a Quality Management System that is registered for compliance to EN ISO 9001:2015. All filters are non-destructively integrity tested and flushed with Purified Water with a maximum conductivity of 1.1 µS/cm @ 20°C (68°F) and a maximum TOC (Total Organic Carbon) content of 0.5 mg (500 ppb) of carbon per liter. They are then dried using HEPA filtered air and sealed in a protective polyethylene bag within the cleanroom. Filters that are provided as pre-wet are not dried, but rather are subjected to a further rinse of ozonated water at 0.2 – 0.3 ppm and then vacuum sealed in a cleanroom grade polyethylene bag. Each filter module is marked with an individual serial number, a lot number, product code which is also shown on both the bag label and on the outer product box, therefore all data concerning materials used and production data are documented, accessible and fully traceable.

Cartridge Integrity Test

Graver Technologies, as part of its quality process, integrity tests all CITADEL filter cartridges before release from manufacturing. The specific test used is a Diffusion Test. If further details for the test method are required, please contact Graver Technologies Technical Service. For an integral cartridge, the air diffusion rate which is a measure of the rate at which air diffuses through the water-filled pores of the membrane, must be below a specified value at the Integrity Test pressure. A cartridge with even a minor defect will exhibit much higher airflow rates when measured by this test.

Test Procedure

1) The filter cartridge is first wetted by completely immersing in 60/40 IPA/de-ionized water mixture for 5 minutes.
2) The water flow is shut off and a pressure of 5 psid (0.34 bard) of compressed air is applied upstream of the filter. Any excess water in the housing passes through the filter and is drained from the downstream side of the housing.
3) The air pressure is increased to the value shown in Table below, "Diffusion Pressure" and the system is allowed to stabilize for 2 minutes
4) The diffusive air flow through the filter system is measured and the filter passes the integrity test only if the diffusion flow value is less than the "Maximum Diffusion" shown in the table below.

Pore Size	Diffusion Test Pressure (psig)	Maximum Diffusion (cc/min) per 10-Inch Cartridge Length	Bubble Point (PSIG)
0.05 µm	22 (1.5 bar)	≤ 90	≥ 28 (1.9 bar)
0.1 µm	18 (1.2 bar)	≤ 50	≥ 22 (1.5 bar)
0.2 µm	12 (0.8 bar)	≤ 50	≥ 15 (1.0 bar)
0.45 µm	5 (0.34 bar)	≤ 50	≥ 6 (0.41 bar)
1.0 µm	3 (0.2 bar)	≤ 50	≥ 4 (0.27 bar)
10 µm	N/A*	N/A	N/A

** The 10 µm media is quite open and thus no practical bubble point or diffusion value is available.*

Flow Rate Testing

To contribute to the overall operating economics of an existing filter system, it is important that process filter cartridges offer high flow rates at low-pressure drops. For new systems, this can also allow a smaller filter housing to be used with a resultant savings in capital cost.

Test Procedure

1) A filter cartridge is wetted with 60/40 IPA/water mixture. An integrity test is performed and the results are recorded. (See Page 4 for Integrity Test Procedure).
2) The cartridge is then flushed with clean water for 15 minutes to remove any residual IPA.
3) The filter system is connected to a source of clean water. The pressure of water can be regulated and was adjusted to 18 psi (1.2 bar).
4) The flow through the filter is adjusted 3 GPM and the pressure recorded. This is repeated for other values up to 10 GPM.
5) The values are averaged over the range and reported out as GPM/PSID.

Results

The filter cartridges at each pore size tested showed flow rates as summarized below, meeting the minimum specifications for that pore size.

Average Flux Data for Citadel 0.05 micron			
Cartridge ID: C22, 23, 3 & 27			
Flowrate (GPM)	Temperature Adjusted flow rate (GPM)	DP (Total - system) (PSID)	Flux (PSID/GPM)
3	2.458	2.200	**0.90**
5	4.097	3.900	**0.95**
7	5.736	5.700	**0.99**

Average Flux Data for Citadel 0.1 micron			
Cartridge ID # 75, 76, 77 & 78			
Flowrate (GPM)	Temperature Adjusted flow rate (GPM)	DP (Total - system) (PSID)	Flux (PSID/GPM)
3	2.55	0.875	**0.34**
5	4.25	1.525	**0.35**
7	5.95	2.222	**0.37**
10	8.5	3.625	**0.42**

Average Flux Data for Citadel 0.2 micron			
Cartridge ID: C1, 11, 13 & 15			
Flowrate (GPM)	**Temperature Adjusted flow rate (GPM)**	**DP (Total - system) (PSID)**	**Flux (PSID/GPM)**
3	2.480	0.575	**0.23**
5	4.133	1.150	**0.28**
7	5.786	1.675	**0.29**
9	7.464	2.300	**0.31**
10	8.266	2.500	**0.30**

Average Flux Data for Citadel 0.45 micron			
Cartridge ID: CTL 0.45 5546 - 002 & 003			
Flowrate (GPM)	**Temperature Adjusted flow rate (GPM)**	**DP (Total - system) (PSID)**	**Flux (PSID/GPM)**
3	2.444	0.10	**0.04**
5	4.074	0.40	**0.10**
7	5.704	0.65	**0.11**
9	7.333	0.80	**0.11**

Average Flux Data for Citadel 1.0 micron			
Cartridge ID: CTL 1.0 5492 - 002 & 003			
Flowrate (GPM)	**Temperature Adjusted flow rate (GPM)**	**DP (Total - system) (PSID)**	**Flux (PSID/GPM)**
3	2.444	0.10	**0.04**
5	4.074	0.10	**0.02**
7	5.704	0.20	**0.04**
9	7.333	0.20	**0.03**

Conclusions

Based on this testing, the typical flow rate/pressure drop characteristics of CITADEL cartridges per 10-inch cartridge length are:

0.05 µm: 1.0 gpm/psid
0.1 µm: 2.7 gpm/psid
0.2 µm: 3.5 gpm/psid
0.45 µm: 9.1 gpm/psid
1.0 µm: >15 gpm/psid*
10 µm: >15 gpm/psid*

** The media is quite open and thus flow resistance is low making. Value far exceeds practical recommendations.*

Cartridge Extraction

Testing was conducted by CT Associates of Eden Prairie MN on a CITADEL cartridge (pre-wet) by flushing with 18 megohm-cm DI water. The cartridge was tested at a flow rate of 2.25 GPM (8.5 LPM).

TOC (Total Organic Carbon)

TOC levels were measured throughout the duration of the test using a GE 500 RL TOC analyzer. The system background showed a TOC level of 0.93 ppb. The test system with the installed cartridge had an initial TOC level of 3.95 ppb and by 2 hours and 30 minutes, the added TOC level was below 1 ppb. Total system TOC levels were below 1 ppb within 8 hours.

NVR (Non-volatile Residue)

Non-volatile residue (NVR) was measured using a Kanomax FMT NRM. The system background showed a NVR level of 0.11 ppb. The test system with the installed cartridge had an initial NVR level of 0.26 ppb and the added NVR was below 0.1 ppb within 78 minutes.

Particle Shedding

Particle shedding from the cartridge was measured over time using Lighthouse NC30+ optical particle counter which is capable of measuring particles as small as 30 nm (0.03 microns).

Particle Cleanliness Summary

Particle Size	*Rinse Time to Conc. Added (h)*		
(nm)	*10 p/mL*	*1 p/mL*	*0.1 p/mL*
30	0.14	0.55	2.21
50	0.05	0.29	1.73
80	0.00	0.00	0.03
100	0.00	0.00	0.00

Resistivity Recovery

Resistivity of the system was measured using a Thornton 200CR conductivity meter. Upon installation, the resistivity measured 18 MΩ-cm. The system returned to baseline levels of 18.2 MΩ-cm within 40 gallons.

During manufacture, each CITADEL filter is wet-out with 60/40 IPA/water and then flushed with semiconductor grade ultrapure water for 15 minutes at a flow rate of 10 GPM, assuring the high purity of each filter shipped. The filters that are provide pre-wet have an additional flush step using ozonated water for 10 minutes. Upon start-up, customers can expect minimal extractable levels (TOC, NVR, resistivity decrease). There are no observable particles at 0.1 micron (100 nm) or above at start-up.

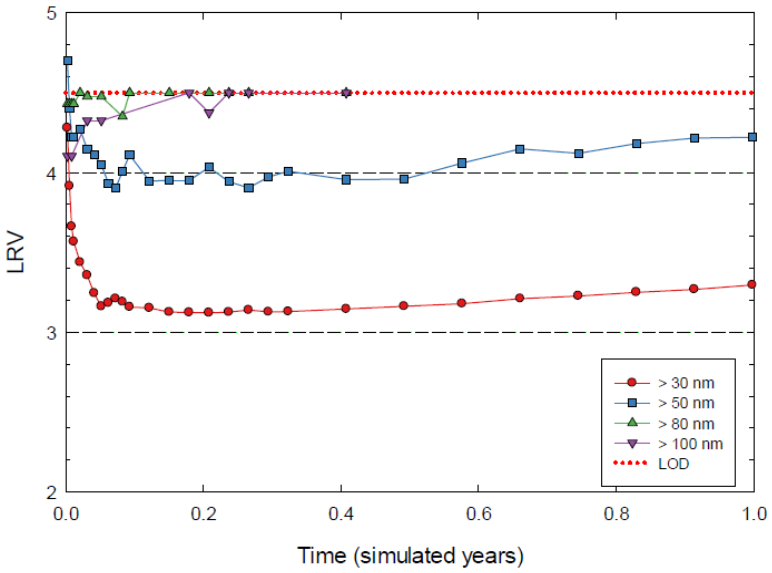
Filter Retention

Testing was conducted by CT Associates of Eden Prairie MN on a 0.05 micron CITADEL cartridge (pre-wet) using a modified version of the test procedure described in the *SEMATECH Provisional Test Method for Determining Particle Contributions and Retention by UPW Distribution System Components* [1]. The cartridges are first flushed with 18 megohm-cm DI water for 72 hours to eliminate/reduce any particles that could shed from the cartridge. The filter is then exposed to 0.1% Triton X-100 solution in DI water to eliminate any potential for charge interactions and further flushed for 2 – 4 hours. The test is performed at a flow rate of 2.6 GPM (10 LPM).

Efficiency Average over 16 hours

Channel Size	***Inlet Particles (#/ml***	***Outlet Particles (#/ml)***	***Retention Efficiency***
30 nm	165.032	116	99.93%
50 nm	67,039	6.93	99.99%
80 nm	17,982	0.34	100.00%
100 nm	8,464	0.19	100.00%

The SEMATECH method measures particle retention in DI water by simulating the quantity of paticles that could be seen during the equivalent of 1-year downstream of a mixed bed ion exchange resin tank. The 1-year challenge is simulated using a 16-hour filter test.



The reduction values (LRV – log reduction value) remain relatively stable over the time frame. It should be noted that even though the filter is rated at 0.05 micron, capture efficiency of 0.03 micron particle is quite high.

Leachables

Two factory flushed CITADEL 0.05 µm filter cartridge samples were submitted to Balazs Analytical Services for metals extractables. An extraction was done with 1.5 liters of 5% HCL or 1.5% ultrapure water (UPW) and the residue analyzed.

- Leachable anions using ion chromatography
- Leachable Low Level 30 Elements in UPW

The test samples were prepped and leached in accordance with SEMI F57-0301 and F40-0699 protocols. The F57-0301 standard requires manufacturers to produce semiconductor fluid handling products that follow best practices in material science and do not contaminate processes with extractable ions, metallics or TOCs- areas which can negatively impact yield and reduce the life of semiconductor equipment. In addition, the standard provides test protocols and product performance requirements. SEMI F40-0699 covers the Practice for Preparing Liquid Chemical Distribution Components for Chemical Testing. Results are reported as ppb (part per billion) of each contaminant.

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Air Liquide Electronics, U.S. LP - Balazs™ Analytical Services
13458 North Central Expressway, MS 301 Dallas TX 76243
Telephone (972) 995-2228 FAX (972) 995-3173 Duty Phone (214) 878-4573

ANALYTICAL TEST RESULTS

Customer Information

Name: Graver technologies, Praveen Jana
Address:
Contact: Praveen Jana
Phone: 302-731-3540 **Fax:**

Product	HYDROCHLORIC-EXTERNAL	Sample Number	1018051
Chemical:	HCL	Status	Authorized
Sample Type		Logged By	AGARCIA
Vessel:		Received Date	6/8/2015 11:00:01AM
Vessel Serial #:		Completed Date:	6/12/2015 6:39:58PM
Lot Number:	C-0.1-7815-004	PO Number	140861
Sample In-Spec:	Yes	Quote # :	None
Date Sample Pulled:	None		
IC Bottle ID:	None	Metals Bottle ID:	None
Description:	HCL extraction of filter leacheable		

DRC_HCL **Authorized** **Approval By: Jerry W. Smith,Production Laboratory Manager**

Test Comments: There are no comments associated with this test

Analysis / Rep	Result Value	Min.	Max.	Units	Entered By	Date Test Completed
Aluminum	1.788			ppb	LABSTATION	6/12/2015 6:39:57PM
Antimony	<0.020			ppb	LABSTATION	6/12/2015 6:39:57PM
Arsenic	<0.025			ppb	LABSTATION	6/12/2015 6:39:57PM
Barium	0.030			ppb	LABSTATION	6/12/2015 6:39:57PM
Beryllium	<0.005			ppb	LABSTATION	6/12/2015 6:39:57PM
Bismuth	0.005			ppb	LABSTATION	6/12/2015 6:39:57PM
Boron	0.034			ppb	LABSTATION	6/12/2015 6:39:57PM
Cadmium	<0.003			ppb	LABSTATION	6/12/2015 6:39:57PM
Calcium	9.326			ppb	BWIDJAJA	6/12/2015 6:39:57PM
Chromium	0.342			ppb	LABSTATION	6/12/2015 6:39:57PM
Cobalt	0.005			ppb	LABSTATION	6/12/2015 6:39:57PM
Copper	0.112			ppb	LABSTATION	6/12/2015 6:39:57PM
Gallium	<0.005			ppb	LABSTATION	6/12/2015 6:39:57PM
Germanium	<0.030			ppb	BWIDJAJA	6/12/2015 6:39:57PM
Gold	<0.080			ppb	BWIDJAJA	6/12/2015 6:39:57PM
Indium	<0.004			ppb	LABSTATION	6/12/2015 6:39:57PM

Iron	4.650	ppb	BWIDJAJA	6/12/2015	6:39:57PM
Lanthanum	<0.004	ppb	LABSTATION	6/12/2015	6:39:57PM
Lead	0.019	ppb	LABSTATION	6/12/2015	6:39:57PM
Lithium	<0.003	ppb	LABSTATION	6/12/2015	6:39:57PM
Magnesium	0.437	ppb	LABSTATION	6/12/2015	6:39:57PM
Manganese	0.058	ppb	LABSTATION	6/12/2015	6:39:57PM
Molybdenum	0.032	ppb	LABSTATION	6/12/2015	6:39:57PM
Nickel	0.473	ppb	LABSTATION	6/12/2015	6:39:57PM
Niobium	<0.003	ppb	LABSTATION	6/12/2015	6:39:57PM
Palladium	<0.060	ppb	LABSTATION	6/12/2015	6:39:57PM
Platinum	<0.020	ppb	LABSTATION	6/12/2015	6:39:57PM
Potassium	1.179	ppb	LABSTATION	6/12/2015	6:39:57PM
Silver	<0.050	ppb	LABSTATION	6/12/2015	6:39:57PM
Sodium	1.867	ppb	LABSTATION	6/12/2015	6:39:57PM
Strontium	0.009	ppb	LABSTATION	6/12/2015	6:39:57PM
Tantalum	<0.015	ppb	LABSTATION	6/12/2015	6:39:57PM
Thallium	<0.003	ppb	LABSTATION	6/12/2015	6:39:57PM
Tin	<0.013	ppb	LABSTATION	6/12/2015	6:39:57PM
Titanium	0.066	ppb	LABSTATION	6/12/2015	6:39:57PM
Tungsten	0.012	ppb	LABSTATION	6/12/2015	6:39:57PM
Vanadium	0.127	ppb	LABSTATION	6/12/2015	6:39:57PM
Zinc	0.830	ppb	LABSTATION	6/12/2015	6:39:57PM
Zirconium	0.019	ppb	LABSTATION	6/12/2015	6:39:57PM

Review Notes: There are no review notes associated with this sample

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ANALYTICAL TEST RESULTS

Customer Information

Name: Graver technologies, Cris Lemay
Address:
Contact:
Phone: 302-824-3828 **Fax:**

Product	DIW_EXTERNAL-External	Sample Number	1011857
Chemical:	DIH2O	Status	Authorized
Sample Type		Logged By	AGARCIA
Vessel:		Received Date	5/4/2015 12:36:33PM
Vessel Serial #:		Completed Date:	5/15/2015 4:22:27PM
Lot Number:	C-0.1-7815-002	PO Number	N/A
Sample In-Spec:	Yes	Quote # :	None
Date Sample Pulled:	None		
IC Bottle ID:	None	Metals Bottle ID:	None
Description:	UPW extraction of Filter. ICP-MS 30 elements		

ICPMS_DIW **Authorized** **Approval By: Jerry W. Smith,Production Laboratory Manager**

Test Comments: There are no comments associated with this test

Analysis / Rep	Result Value	Min.	Max.	Units	Entered By	Date Test Completed
Aluminum	0.470			ppb	LABSTATION	5/15/2015 4:22:27PM
Antimony	<0.004			ppb	LABSTATION	5/15/2015 4:22:27PM
Arsenic	<0.007			ppb	LABSTATION	5/15/2015 4:22:27PM
Barium	0.025			ppb	LABSTATION	5/15/2015 4:22:27PM
Beryllium	<0.005			ppb	LABSTATION	5/15/2015 4:22:27PM
Bismuth	<0.005			ppb	LABSTATION	5/15/2015 4:22:27PM
Boron	0.083			ppb	LABSTATION	5/15/2015 4:22:27PM
Cadmium	<0.004			ppb	LABSTATION	5/15/2015 4:22:27PM
Calcium	8.211			ppb	NPHUNG	5/15/2015 4:22:27PM
Calcium	8.950			ppb	NPHUNG	5/15/2015 4:22:27PM
Chromium	0.013			ppb	LABSTATION	5/15/2015 4:22:27PM
Cobalt	0.004			ppb	LABSTATION	5/15/2015 4:22:27PM
Copper	0.045			ppb	LABSTATION	5/15/2015 4:22:27PM
Gallium	<0.004			ppb	LABSTATION	5/15/2015 4:22:27PM
Germanium	0.010			ppb	LABSTATION	5/15/2015 4:22:27PM
Gold	<0.005			ppb	LABSTATION	5/15/2015 4:22:27PM

Indium	<0.004	ppb	LABSTATION	5/15/2015 4:22:27PM
Iron	0.424	ppb	LABSTATION	5/15/2015 4:22:27PM
Lanthanum	<0.003	ppb	LABSTATION	5/15/2015 4:22:27PM
Lead	0.011	ppb	LABSTATION	5/15/2015 4:22:27PM
Lithium	<0.004	ppb	LABSTATION	5/15/2015 4:22:27PM
Magnesium	0.307	ppb	LABSTATION	5/15/2015 4:22:27PM
Manganese	0.020	ppb	LABSTATION	5/15/2015 4:22:27PM
Molybdenum	0.005	ppb	LABSTATION	5/15/2015 4:22:27PM
Nickel	0.076	ppb	LABSTATION	5/15/2015 4:22:27PM
Niobium	<0.005	ppb	LABSTATION	5/15/2015 4:22:27PM
Palladium	<0.003	ppb	LABSTATION	5/15/2015 4:22:27PM
Platinum	<0.009	ppb	LABSTATION	5/15/2015 4:22:27PM
Potassium	0.674	ppb	LABSTATION	5/15/2015 4:22:27PM
Silver	<0.006	ppb	LABSTATION	5/15/2015 4:22:27PM
Sodium	1.128	ppb	LABSTATION	5/15/2015 4:22:27PM
Sodium	1.185	ppb	NPHUNG	5/15/2015 4:22:27PM
Strontium	0.005	ppb	LABSTATION	5/15/2015 4:22:27PM
Tantalum	<0.008	ppb	LABSTATION	5/15/2015 4:22:27PM
Thallium	<0.002	ppb	LABSTATION	5/15/2015 4:22:27PM
Tin	<0.004	ppb	LABSTATION	5/15/2015 4:22:27PM
Titanium	0.105	ppb	LABSTATION	5/15/2015 4:22:27PM
Tungsten	0.006	ppb	LABSTATION	5/15/2015 4:22:27PM
Vanadium	0.043	ppb	LABSTATION	5/15/2015 4:22:27PM
Zinc	0.281	ppb	LABSTATION	5/15/2015 4:22:27PM
Zirconium	<0.012	ppb	LABSTATION	5/15/2015 4:22:27PM

Review Notes: There are no review notes associated with this sample

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Endotoxin Test

Endotoxins are complex polysaccharide molecules (LPS) composed of lipid (lipid A) and polysaccharide sides chains and are integral components of the outer membrane of gram negative bacteria. These molecules are not secreted but are released only when the cells are disrupted or destroyed. Above certain levels, endotoxins elicit an antigenic response, resulting in fever and altered resistance to bacterial infections. Because of this sensitivity, it is important to monitor products which may contact fluids that could be administered to humans or animals.

The detection of endotoxins is accomplished using Limulus Amebocyte Lysate (LAL) Kinetic Chromogenic Assay. In this test, a filter element is extracted with non-pyrogenic Water for Injection (WFI). Endotoxin levels in the extracted fluid are then measured spectrophotometrically and compared to standard concentrations. These values are reported as EU/ml (Endotoxin Units/ml).

Results

NAMSA of Northwood Ohio conducted the testing on a sample of Citadel. Levels were reported at 0.005 EU/ml and 5.05 EU/device. This level is well below the criteria established by the US FDA of 0.5 EU/ml and the USP requirement of 20 EU/device.

RESULTS

Test Article Extract Dilution:	1
Positive Product Control Percent Recovery:	117% (between 50% and 200% is acceptable)
Test Article Extract:	< 0.00500 EU/mL (Total Concentration) < 5.05 EU/device

TEST ACCEPTANCE CRITERIA

Type of Product	Current FDA Requirements	Current USP Requirements
Anterior Segment Solid Intraocular Device	Less than or equal to 0.2 EU/device	Not Applicable
Medical Device	Less than or equal to 0.5 EU/mL*	Less than or equal to 20.0 EU/device
Medical Device Contacting Cerebrospinal Fluid	Less than or equal to 0.06 EU/mL*	Less than or equal to 2.15 EU/device
Water for Injection	Not Applicable	Less than or equal to 0.25 EU/mL

*Based on an extraction volume of 40 mL/device

European Regulation No 1935/2004 and European Regulation 10/2011

The underlying principle of these regulations is to ensure that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change or deterioration in the composition or properties of the food. Tests for migration behavior in direct food contact were conducted by Belgium Packaging Institute in a variety of liquids to simulate aqueous, acidic, alcoholic, and fatty foodstuffs.

Results

The test results indicate that the overall migration of all of the individual parts will not exceed the overall migration limit of 10 mg/dm^2 or 60 mg/kg foodstuffs for simulant A (10% ethanol, representing all aqueous foodstuffs), simulant B (3% acetic acid, representing all foodstuffs with a pH below 4.5) and simulant D2 (95% ethanol and isooctane instead of olive oil representing all fatty foodstuffs) using the given conditions. In accordance with the European Regulation No 10/2011 and amendments, conformity with the overall migration limit for simulants A, B and D2 demonstrates suitability for contact with all kinds of foodstuffs.

NOTES