ULTRAFILTER
THE FILTRATION MANUFACTURER

Kronsbein ultrafilter ®

PF-PES

Filter Cartridges | Validation Guide

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PF-PES

CONTENT

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VALIDATION GUIDE

INTRODUCTION

Ultrafilter PF-PES series cartridge filters contain 0.20 µm, 0.45 µm, 0.65 µm or 1.2 µm hydrophilic polyethersulfone (PES) membrane, which are designed for different filtration processes in food and beverage industry. The purpose of this report is to summarize tests done to qualify the performance of Ultrafilter PF-PES series cartridge filters under laboratory conditions.

Quality Assurance

Ultrafilter GmbH establishes and continuously maintains the company's quality assurance system in accordance with the requirements of ISO 9001:2015 quality management system. All the products are manufactured under strict quality system to ensure stable and reliable quality.

Raw Material Control

Ultrafilter GmbH has established a rigorous supplier selection and periodic evaluation system. The core materials are selected from internationally renowned raw material suppliers and manage the suppliers hierarchically. The injection molding pellets, support layers, O-rings and other materials or components are inspected according to the company's internal control standards to ensure the quality of raw materials is stable and reliable.

Environment Management

The entire manufacturing process of the Ultrafilter filter from raw material storage to product packaging is completed in the ISO Class 8 clean area, which ensures the cleanliness of the product and prevents pollution. The air purification system is confirmed and maintained regularly to ensure that the cleanliness of environment continuously meets the requirements of ISO Class 8. The suspended particles, sedimentation bacteria, temperature, humidity and differential pressure are monitored periodically to provide for a highly controlled clean environment.

Lot Release and Traceability

The sterilizing grade Ultrafilter filter requires 100% integrity testing before delivery. The test methods include bubble point, diffusion flow and water intrusion. The specific test method can be found in the integrity test section of the quality certificate.

The product lot number and serial number of Ultrafilter filter are engraved on the cartridge cage. Customers can also find the corresponding product lot number in the product label and quality certificate. The product can be traced from the whole process of raw materials, equipment, manufacturing process through the lot number and serial number.

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PF-PES

PRODUCT SPECIFICATIONS

CATALOGUE NUMBERS DESCRIPTION

PF-PES

	PORE SIZE	FILTER LENGTH	CARTRIDGE ADAPTER TYPE	SEAL MATERIAL
	20 = 0.20 µm	05 = 5"	2 = Code 2	A = EPDM
	45 = 0.45 µm	10 = 10"	3 = Code 3	B = Silicone
	65 = 0.65 µm	20 = 20"	7 = Code 7	G = Fluoroelastomer
	120 = 1.20 µm	30 = 30"	8 = Code 8	
		40 = 40"	MF = DOE	
			UF = UF	

Example Part Number:	Filter-Type	Pore size	Filter Lenght	Connection Type	Sealing	Pharma Grade
	PF-PES	45	30	7	-B	-V

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VALIDATION GUIDE

SPECIFICATIONS		
FILTER	**PF-PES 0.20 µm**	**PF-PES 0.45 µm**
LENGTH	254.0 MM (10 INCH)	
DIAMETER	69.0 MM (2.7 INCH)	
MATERIALS OF CONSTRUCTION		
FILTER MEMBRANE	POLYETHERSULFONE (PES)	
SUPPORTS	POLYPROPYLENE	
CORE, CAGE, END CAPS	POLYPROPYLENE	
ADAPTER INTERNAL SUPPORT	STAINLESS STEEL 316L, PBT	
O-RINGS	SILICONE, EPDM, FLUOROELASTOMER	
PORE SIZE	0.20 µm	0.45 µm
EFFECTIVE FILTRATION AREA	0.60 M^2 (6.5 FT^2)	0.58 M^2 (6.2 FT^2)
MAXIMUM OPERATING PRESSURE	6.9 BAR (100 PSI) AT 25 °C 2.4 BAR (35 PSI) AT 80 °C	
MAXIMUM DIFFERENTIAL PRESSURE		
FORWARD	6.9 BAR (100 PSI) AT 25 °C 2.4 BAR (35 PSI) AT 80 °C	
REVERSE	3.0 BAR (44 PSI) AT 25 °C 1.0 BAR (15 PSI) AT 80 °C	
WATER BUBBLE POINT AT 20 °C	⩾ 3.4 bar (49 psi), air	⩾ 2.2 bar (32 psi), air
AIR DIFFUSION AT 20 °C	Wetted with water: ⩽ 30 mL/min at 2.5 bar (36 psi)	Wetted with water: ⩽ 28 mL/min at 1.6 bar (23 psi)
BACTERIAL RETENTION PF-PES 0.20 µm	RETENTION OF 107 CFU/CM2 BREVUNDIMONAS DIMINUTA (ATCC® 19146) ACCORDING TO ASTM F838.	
STERILIZATION		
STEAM IN PLACE	CAN BE STEAM STERILIZED 55 CYCLES FOR 30 MINUTES AT 135 °C (< 0.3 BAR, 5 PSI).	
AUTOCLAVE	CAN BE AUTOCLAVED 200 CYCLES FOR 30 MINUTES AT 130 °C.	
HOT WATER SANITIZATION	CAN BE HOT WATER SANITIZED FOR 30 MINUTES AT 85 °C WITH 50 CYCLES.	
CHEMISTRY SANITIZATION	CAN BE SANITIZED FOR 30 MINUTES AT 40 °C WITH 50 CYCLES IN A MIXED SOLUTION OF SODIUM HYPOCHLORITE (NACLO, 100 PPM) AND PEROXYACETIC ACID (100 PPM).	
INDIRECT FOOD ADDITIVE	ALL COMPONENT MATERIALS MEET THE FDA INDIRECT FOOD ADDITIVE REQUIREMENTS CITED IN 21 CFR 177–182.	
QUALITY ASSURANCE	THESE PRODUCTS ARE MANUFACTURED IN A FACILITY WHICH ADHERES TO ISO 9001:2015 PRACTICES.	

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PF-PES

SPECIFICATIONS

FILTER	PF-PES 0.65 µm	PF-PES 1.2 µm
LENGTH	254.0 MM (10 INCH)	
DIAMETER	69.0 MM (2.7 INCH)	
MATERIALS OF CONSTRUCTION		
FILTER MEMBRANE	POLYETHERSULFONE (PES)	
SUPPORTS	POLYPROPYLENE	
CORE, CAGE, END CAPS	POLYPROPYLENE	
ADAPTER INTERNAL SUPPORT	STAINLESS STEEL 316L, PBT	
O-RINGS	SILICONE, EPDM, FLUOROELASTOMER	
PORE SIZE	0.65 µm	1.2 µm
EFFECTIVE FILTRATION AREA	0.58 M² (6.2 FT²)	0.58 M² (6.2 FT²)
MAXIMUM OPERATING PRESSURE	6.9 BAR (100 PSI) AT 25 °C 2.4 BAR (35 PSI) AT 80 °C	
MAXIMUM DIFFERENTIAL PRESSURE		
FORWARD	6.9 BAR (100 PSI) AT 25 °C 2.4 BAR (35 PSI) AT 80 °C	
REVERSE	3.0 BAR (44 PSI) AT 25 °C 1.0 BAR (15 PSI) AT 80 °C	
WATER BUBBLE POINT AT 20 °C	⩾ 1.2 bar (17 psi), air	⩾ 0.5 bar (7 psi), air
AIR DIFFUSION AT 20 °C	Wetted with water: ⩽ 20 mL/min at 1.0 bar (17 psi)	Wetted with water: ⩽ 20 mL/min at 4.4 bar (5.8 psi)
BACTERIAL RETENTION PF-PES 0.20 µm	RETENTION OF 107 CFU/CM2 BREVUNDIMONAS DIMINUTA (ATCC® 19146) ACCORDING TO ASTM F838.	
STERILIZATION		
STEAM IN PLACE	CAN BE STEAM STERILIZED 55 CYCLES FOR 30 MINUTES AT 135 °C (< 0.3 BAR, 5 PSI).	
AUTOCLAVE	CAN BE AUTOCLAVED 200 CYCLES FOR 30 MINUTES AT 130 °C.	
HOT WATER SANITIZATION	CAN BE HOT WATER SANITIZED FOR 30 MINUTES AT 85 °C WITH 50 CYCLES.	
CHEMISTRY SANITIZATION	CAN BE SANITIZED FOR 30 MINUTES AT 40 °C WITH 50 CYCLES IN A MIXED SOLUTION OF SODIUM HYPOCHLORITE (NACLO, 100 PPM) AND PEROXYACETIC ACID (100 PPM).	
INDIRECT FOOD ADDITIVE	ALL COMPONENT MATERIALS MEET THE FDA INDIRECT FOOD ADDITIVE REQUIREMENTS CITED IN 21 CFR 177–182.	
QUALITY ASSURANCE	THESE PRODUCTS ARE MANUFACTURED IN A FACILITY WHICH ADHERES TO ISO 9001:2015 PRACTICES.	

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VERIFICATION AND VALIDATION

1. Bacteria Challenge Test (BCT)

The USP<1229.4 > defines "A sterilizing-grade filter is one that is capable of retaining a minimum 1×107 cfu of B. diminuta (ATCC® 19146) per square centimeter of effective filter area when tested in accordance with ASTM® F838-05 (2013), Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration."

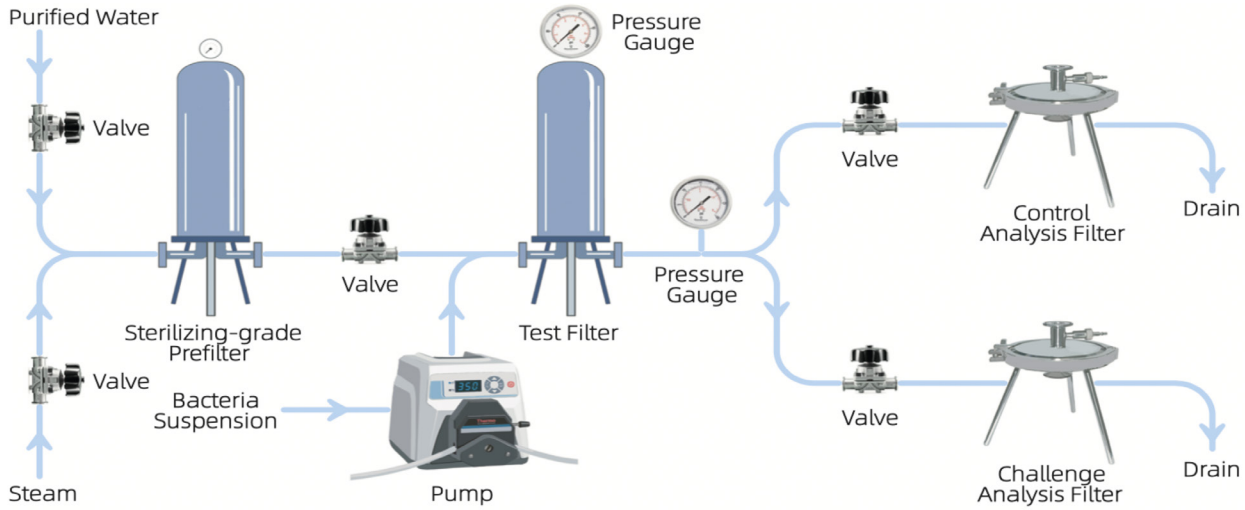
A liquid bacteria challenge test (BCT) was performed to confirm that Ultrafilter PF-PES 0.20 µm cartridge filter can completely retain a minimum concentration of 107 cfu/cm2 (EFA) Brevundimonas diminuta (ATCC® 19146) and meet the criteria for sterilizing grade performance as defined in ASTM methodology.

Summary of Method

Ultrafilter PF-PES 0.20 µm cartridge filters were wetted with water and steamed at 135 °C for 30 minutes prior to testing. The cartridge filters were subjected to integrity test and then challenged with Brevundimonas diminuta (ATCC® 19146) of the challenge level over 1×107 cfu/cm2 (EFA) in accordance with ASTM F838 at a pressure of 2 bar.

After the bacteria challenge test, the control analysis filter and challenge analysis filters are incubated on Tryptic Soy Agar (TSA) plates at 30 °C to determine if there are any challenge bacteria passing through the tested filter. The analysis is conducted according to ASTM methodology.

Particle Retention Ratings (µm)



PF-PES

Results

LOT NUMBER	DIFFUSION @ 2.5 BAR (ML/MIN)	CHALLENGE LEVEL (CFU/10-INCH)	FILTRATE STERILITY	LRV/CM²
A140028309	9.3	1.20×10^{11}	Sterile	7.30
A140378510	10.1	9.05×10^{10}	Sterile	7.18
A140388510	11.3	1.20×10^{11}	Sterile	7.30
A140398510	12.4	6.98×10^{10}	Sterile	7.07
A140408510	14.2	8.13×10^{10}	Sterile	7.13
A140418510	15.8	9.05×10^{10}	Sterile	7.18
A140618526	15.9	8.01×10^{10}	Sterile	7.13
A140628526	16.5	1.20×10^{11}	Sterile	7.30
A141058620	17.7	1.16×10^{11}	Sterile	7.29
A141268628	18.2	1.74×10^{11}	Sterile	7.46
A141278628	18.5	1.42×10^{11}	Sterile	7.37
A141818723	18.9	8.01×10^{10}	Sterile	7.13

Conclusion

Ultrafilter PF-PES 0.20 µm cartridge filter can retain a minimum concentration of 107 cfu/cm2 Brevundimonas diminuta (ATCC® 19146) with a sterile filtrate.

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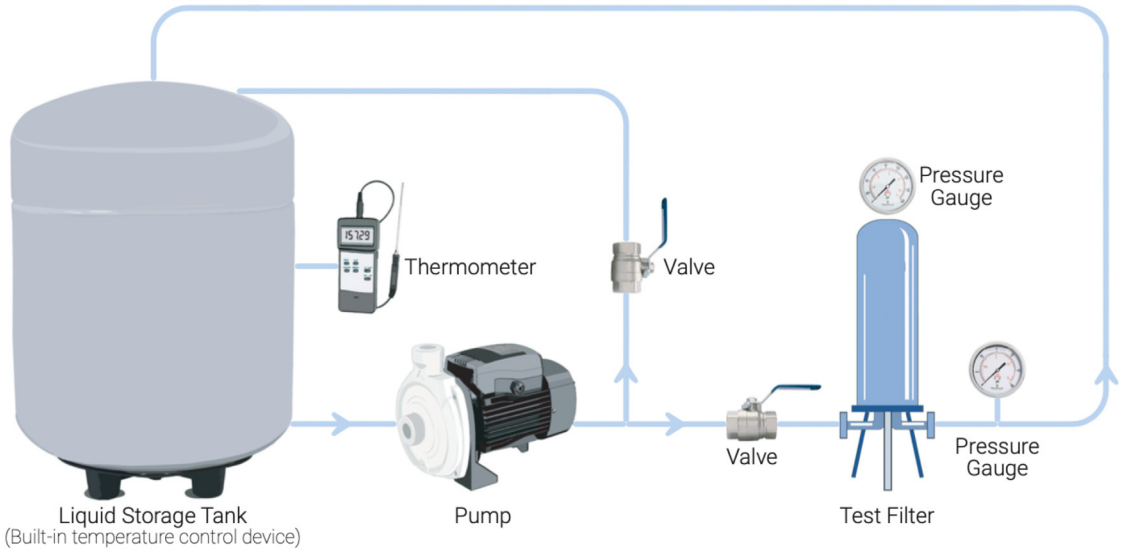
2. Hydraulic Stress

The maximum operating pressure and maximum differential pressure of the filter element at a specific temperature depend on its pressure resistance. The hydraulic stress test is to confirm the pressure resistance of the filter at a specific temperature under the worst-case simulated conditions.

The mechanical and structural features determine the high risk of reverse-use of the filter causing struc- tural damage. It is not recommended to use the filter in reverse direction in the actual production process. The reverse test conditions in this validation test are only the worst-case simulation of the instantaneous reverse pressure difference that may occur in the actual production process, and cannot be used as the basis for the reverse use of the filter.

Hydraulic Stress Test Schematic



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2.1. Hydraulic Stress Test at 25 °C

Summary of Method

Ultrafilter PF-PES series cartridge filters were wetted with water and steamed at 135 °C for 30 minutes prior to testing. The filters were wetted with water and then integrity tested.

The filters were plugged with test dust to increase the differential pressure across the upstream and downstream of the filter. A hydraulic stress of 6.9 bar was applied to the filters at 25 °C for 30 minutes in the forward direction with 10 cycles. Then a differential pressure of 3.0 bar was applied to the filters at 25 °C for 10 minutes in the reverse direction with 3 cycles.

The filter integrity test was carried out to find any changes during the hydraulic stress test.

Ultrafilter PF-PES 0.20 µm cartridge filter

LOT NUMBER	PRIOR TO HYDRAULIC STRESS		POST HYDRAULIC STRESS	
	BUBBLE POINT (BAR)	DIFFUSION @ 2.5 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 2.5 BAR (ML/MIN)
A141268628	4.425	10.9	4.496	11.0
A141278628	4.633	11.4	4.612	11.1
A141818723	4.644	9.3	4.696	9.1

Ultrafilter PF-PES 0.45 µm cartridge filter

LOT NUMBER	PRIOR TO HYDRAULIC STRESS		POST HYDRAULIC STRESS	
	BUBBLE POINT (BAR)	DIFFUSION @ 1.6 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 1.6 BAR (ML/MIN)
JAK1298B06	3.755	6.8	3.860	6.9
JAK1528B15	3.715	9.6	3.786	9.4
JAK1048521	3.727	10.1	3.715	10.2

Ultrafilter PF-PES 0.65 µm cartridge filter

LOT NUMBER	PRIOR TO HYDRAULIC STRESS		POST HYDRAULIC STRESS	
	BUBBLE POINT (BAR)	DIFFUSION @ 1.0 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 1.0 BAR (ML/MIN)
D016408921	2.138	8.8	2.141	8.8
D016188921	2.226	10.7	2.169	10.5
D016528605	2.293	9.5	2.229	9.5

Conclusion

Ultrafilter PF-PES series cartridge filters maintain integrity after a series of hydraulic stress tests at 25 °C described above.

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2.2. Hydraulic Stress Test at 80 °C

Summary of Method

Ultrafilter PF-PES series cartridge filters were wetted with water and steamed at 135 °C for 30 minutes prior to testing. The filters were wetted with water and then integrity tested.

The filters were plugged with test dust to increase the differential pressure across the upstream and downstream of the filter. A hydraulic stress of 2.4 bar was applied to the filters at 80 °C for 30 minutes in the forward direction with 4 cycles. Then a differential pressure of 1.0 bar was applied to the filters at 80 °C for 10 minutes in reverse direction with 3 cycles.

The filter integrity test was carried out to find any changes during the hydraulic stress test.

Ultrafilter PF-PES 0.20 µm cartridge filter

LOT NUMBER	PRIOR TO HYDRAULIC STRESS		POST HYDRAULIC STRESS	
	BUBBLE POINT (BAR)	DIFFUSION @ 2.5 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 2.5 BAR (ML/MIN)
A141268628	4.612	10.4	4.430	10.6
A141278628	4.606	10.3	4.706	10.4
A141818723	4.540	9.4	4.407	9.7

Ultrafilter PF-PES 0.45 µm cartridge filter

LOT NUMBER	PRIOR TO HYDRAULIC STRESS		POST HYDRAULIC STRESS	
	BUBBLE POINT (BAR)	DIFFUSION @ 1.6 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 1.6 BAR (ML/MIN)
JAK1298B06	3.793	7.1	3.754	7.0
JAK1528B15	3.711	10.4	3.738	10.5
JAK1048521	3.742	10.4	3.822	10.1

Ultrafilter PF-PES 0.65 µm cartridge filter

LOT NUMBER	PRIOR TO HYDRAULIC STRESS		POST HYDRAULIC STRESS	
	BUBBLE POINT (BAR)	DIFFUSION @ 1.0 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 1.0 BAR (ML/MIN)
D016408921	2.151	9.2	2.132	9.1
D016188921	2.349	8.9	2.373	8.9
D016528605	2.232	11.6	2.156	11.9

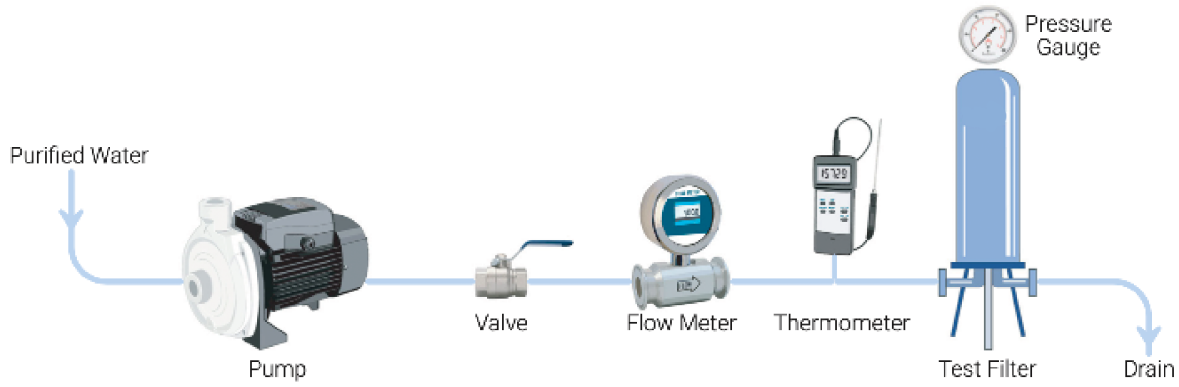
Conclusion

Ultrafilter PF-PES series cartridge filters maintain integrity after a series of hydraulic stress tests at 80 °C described above.

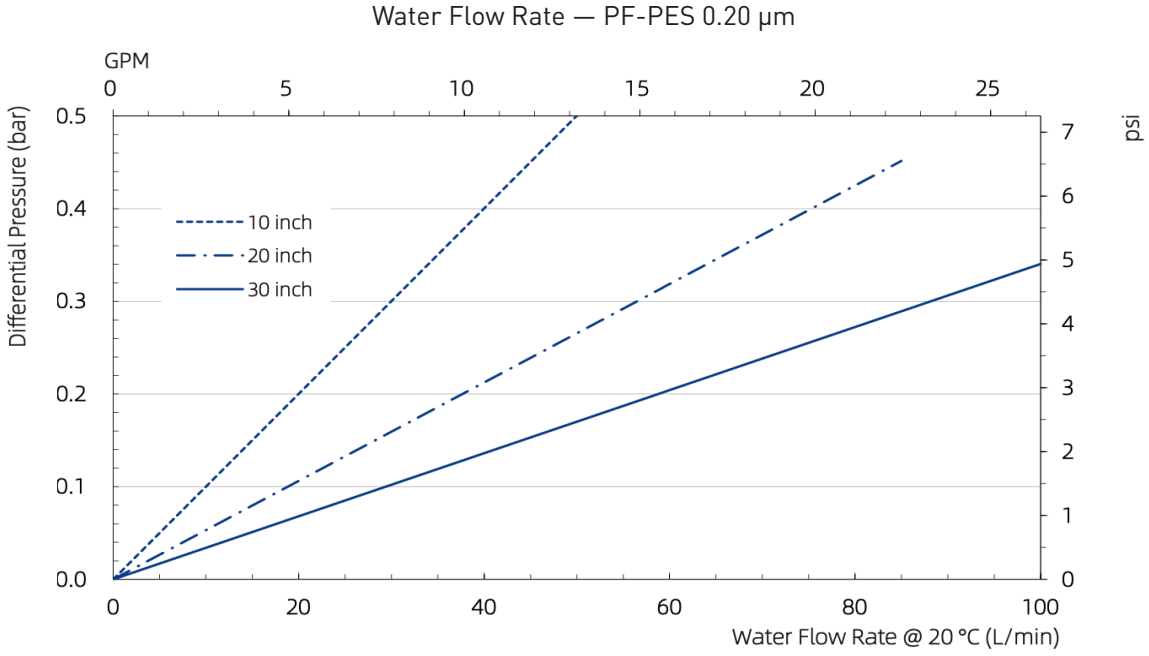
3. Water Flow Rate

Ultrafilter PF-PES sseries cartridge filters were wetted with water and steamed at 135 °C for 30 minutes and integrity tested prior to testing. The required differential pressure for the test is acquired by adjusting the inlet valve of the filter. After achieving a constant differential pressure, the flow rate and water tempera- ture were recorded. All the results of filters were corrected to a water temperature of 20 °C. The graph was plotted after the pressure drop were measured from the filters at various water flow rates.

Water Flow Rate Test Schematic



Results



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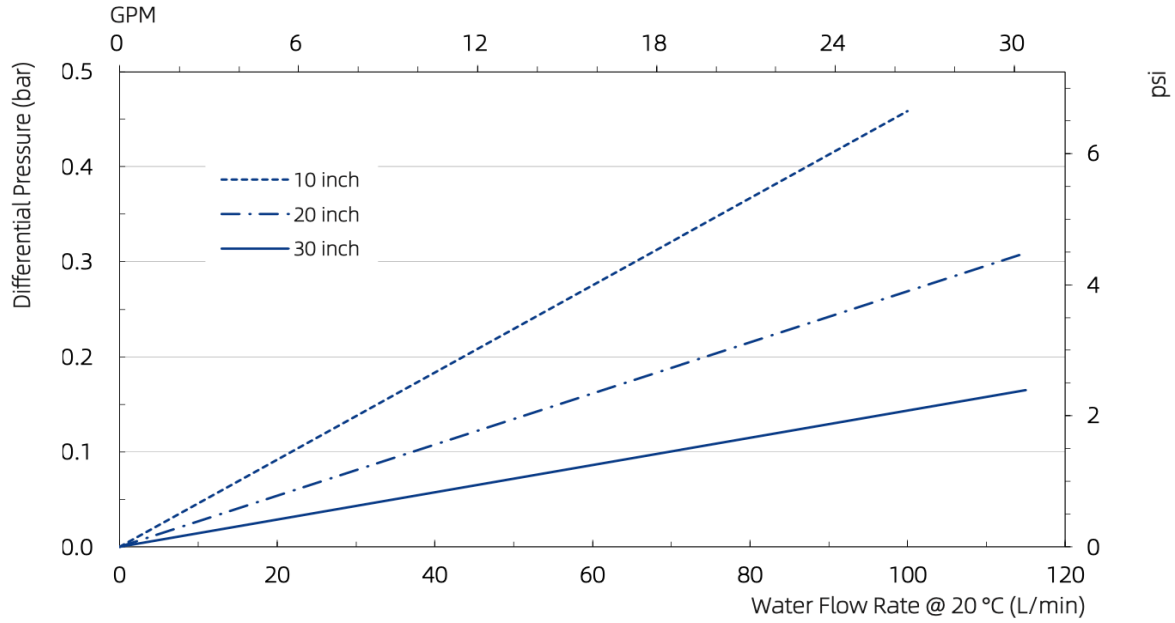
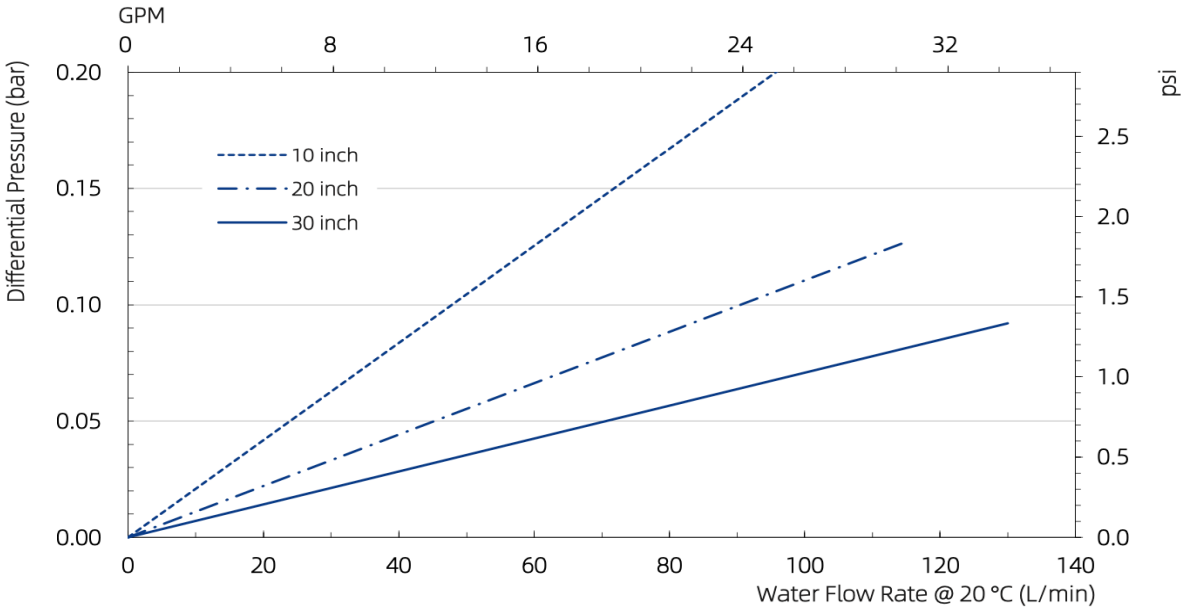
Water Flow Rate — PF-PES 0.42 µm



Water Flow Rate — PF-PES 0.65 µm



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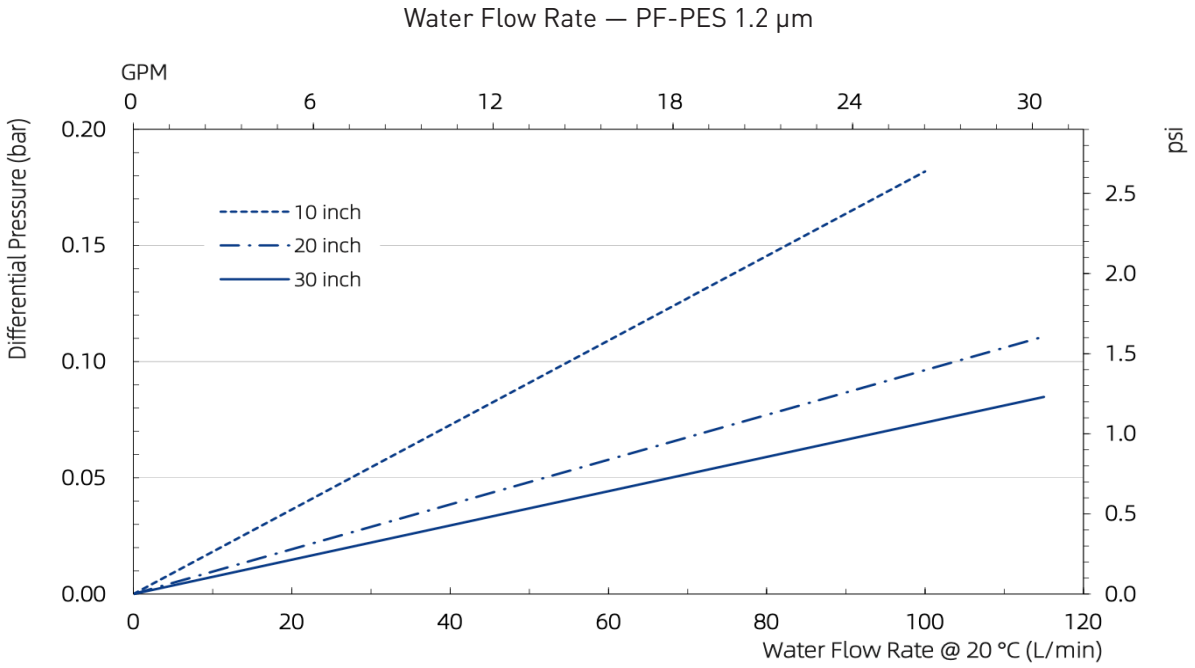
PF-PES



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4. Thermal Resistance

Ultrafilter PF-PES series cartridge filters can be either steamed in place (SIP) or autoclaved. Since multiple sterilization cycles may be required in actual use, the influences of the sterilization on the performances of Ultrafilter PF-PES series cartridge filters were examined. As a result, recommendations and limits for multiple sterilization are given below.

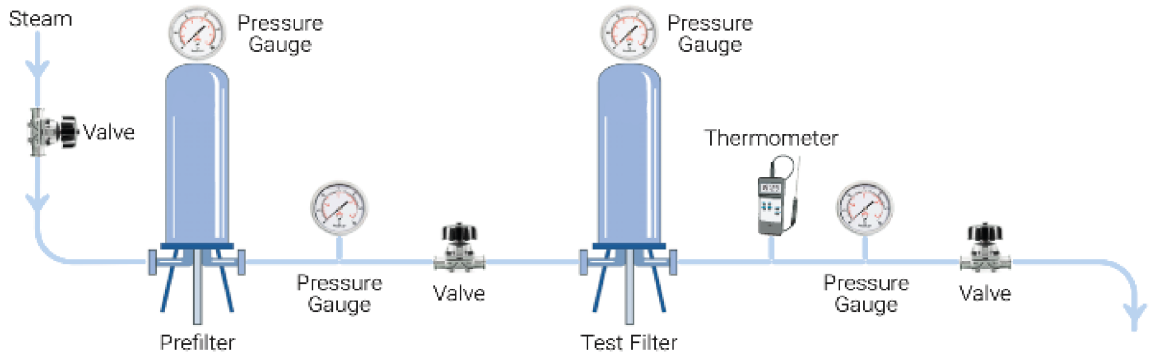
Ultrafilter PF-PES series cartridge filters were wetted with water and subjected to integrity test prior to testing.

Ultrafilter PF-PEScartridge filters were wetted with water and installed in the steam sterilization device in the forward direction. The steam valve and downstream valve were slowly adjusted to increase the tempera- ture to 135 °C as the same time ensuring the differential pressure across the upstream and downstream of the filter less than 0.3 bar. The cartridge filters were steam sterilized at a constant temperature of 135 °C for 30 minutes. After a 30-minute steam sterilization, closed the steam valve and slowly adjusted the downstream valve to release steam pressure. The steam sterilization device was cooled by dry compressed air or natural cooling. Continually monitored the differential pressure across the upstream and downstream of the filter within 0.3 bar during the whole process of temperature rise, sterilization and cooling. The sequence was repeated until the 55 SIP cycles had been achieved for each filter.

Ultrafilter PF-PES cartridge filters were water wetted and wrapped with tinfoil or cleansteam bag. The cartridge filters were autoclaved 200 cycles at 130 °C for 30 minutes.

The filters were validated by integrity test to analyze and evaluate the influences of multiple sterilization.

Schematic of Steam-in-Place



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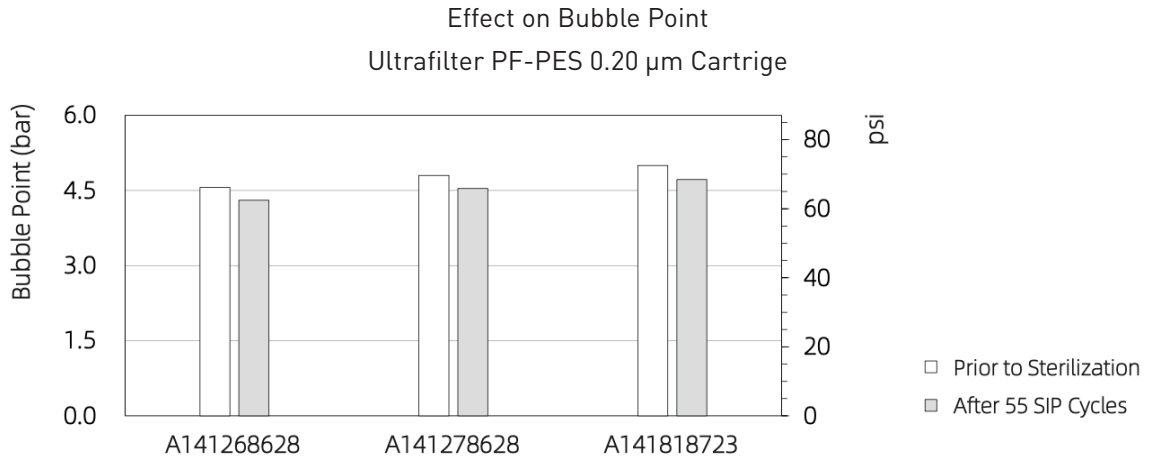
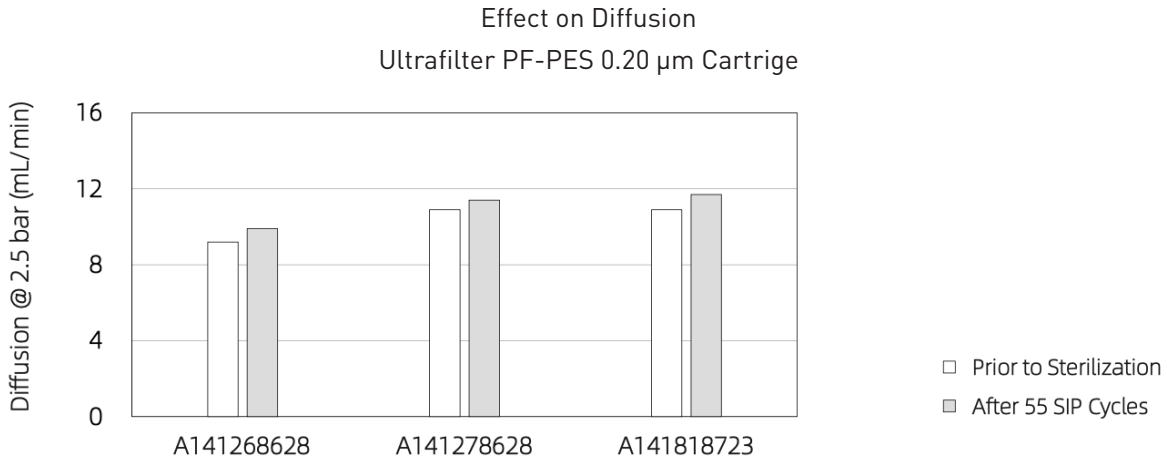
4.1 Ultrafilter PF-PES 0.20 µm cartridge filter

LOT NUMBER	PRIOR TO STERILIZATION		AFTER 55 SIP CYCLES	
	BUBBLE POINT (BAR)	DIFFUSION @ 2.5 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 2.5 BAR (ML/MIN)
A141268628	4.563	9.2	4.306	9.9
A141278628	4.801	10.9	4.540	11.4
A141818723	5.000	10.9	4.721	11.7



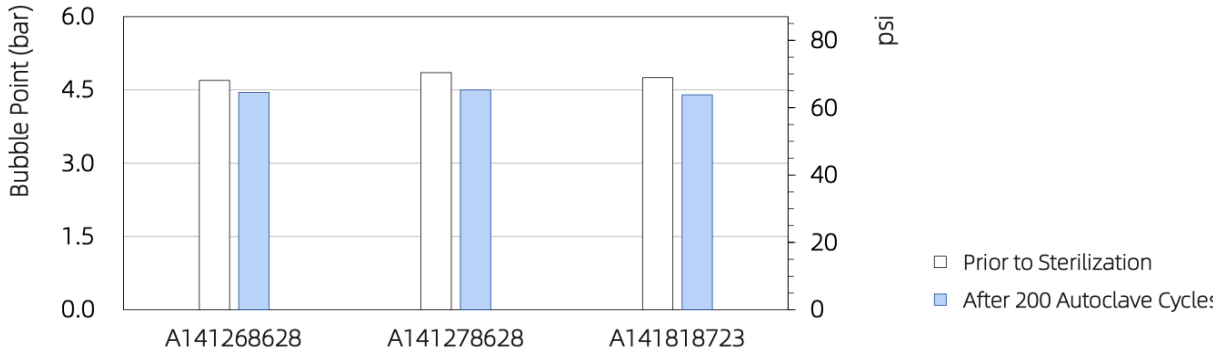


Autoclave

LOT NUMBER	PRIOR TO STERILIZATION		AFTER 200 AUTOCLAVE CYCLES	
	BUBBLE POINT (BAR)	DIFFUSION @ 2.5 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 2.5 BAR (ML/MIN)
A141268628	4.692	10.5	4.449	11.2
A141278628	4.854	11.3	4.497	11.9
A141818723	4.748	10.4	4.399	11.1

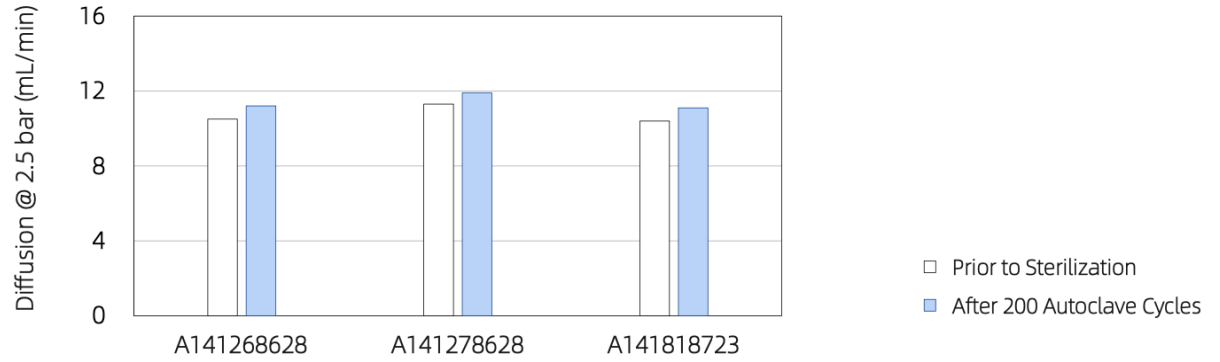
Effect on Bubble Point

Ultrafilter PF-PES 0.20 µm Cartrige



Effect on Diffusion

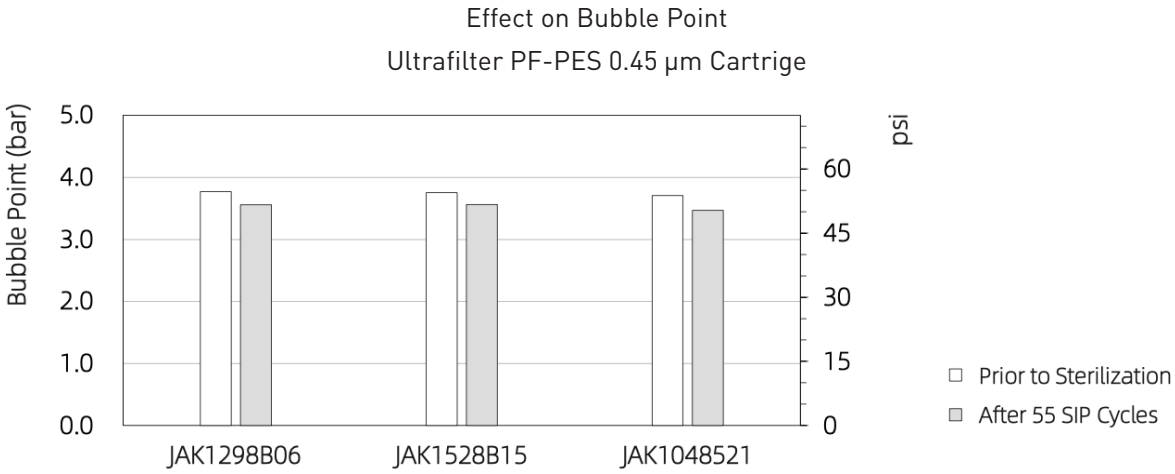
Ultrafilter PF-PES 0.20 µm Cartrige

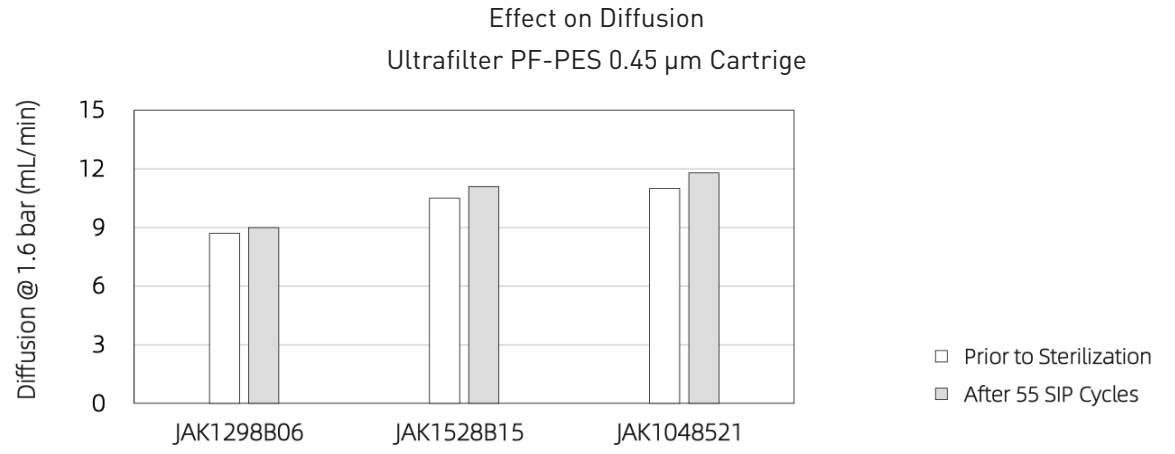


PF-PES

4.1 Ultrafilter PF-PES 0.45 µm cartridge filter

LOT NUMBER	PRIOR TO STERILIZATION		AFTER 55 SIP CYCLES	
	BUBBLE POINT (BAR)	DIFFUSION @ 1.6 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 1.6 BAR (ML/MIN)
JAK1298B06	3.769	8.7	3.559	9.0
JAK1528B15	3.753	10.5	3.564	11.1
JAK1048521	3.707	11.0	3.470	11.8





ULTRAFILTER
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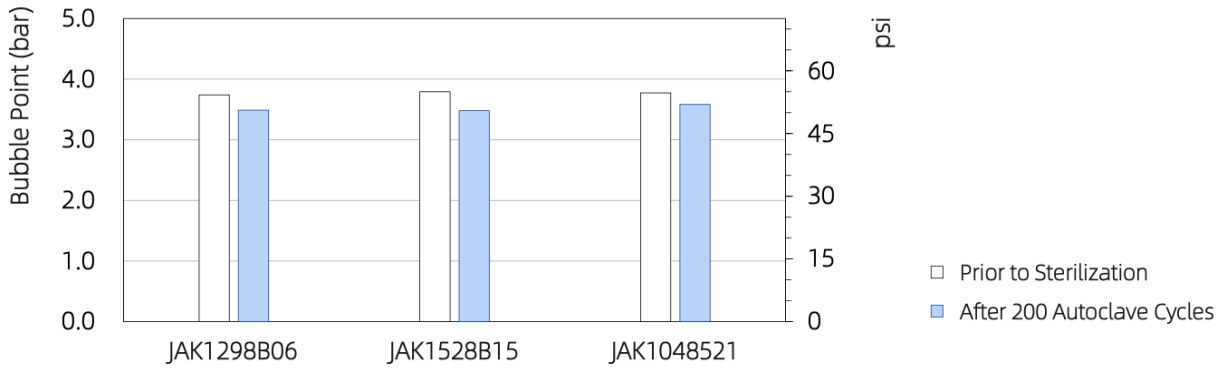
Autoclave

LOT NUMBER	PRIOR TO STERILIZATION		AFTER 200 AUTOCLAVE CYCLES	
	BUBBLE POINT (BAR)	DIFFUSION @ 1.6 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 1.6 BAR (ML/MIN)
JAK1298B06	3.741	6.9	3.488	7.5
JAK1528B15	3.792	10.8	3.479	11.5
JAK1048521	3.774	11.0	3.582	11.9

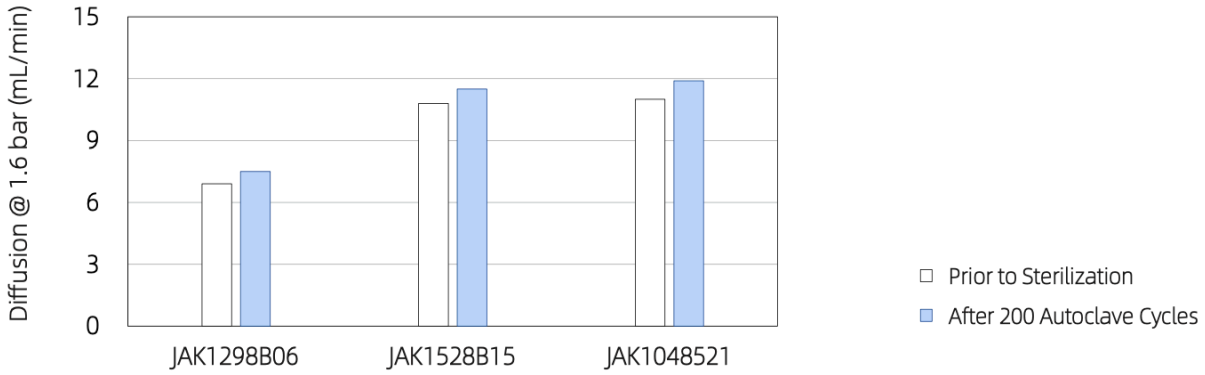
Effect on Bubble Point

Ultrafilter PF-PES 0.45 µm Cartrige



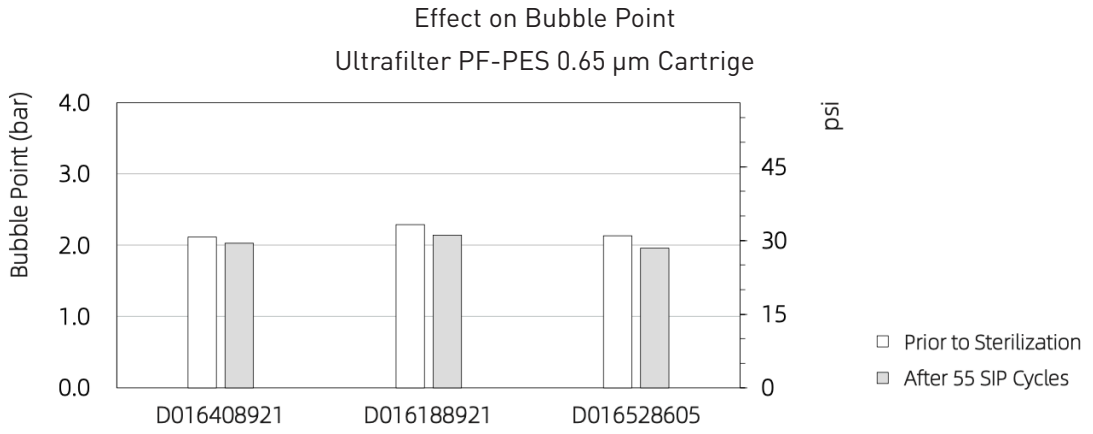
Effect on Diffusion

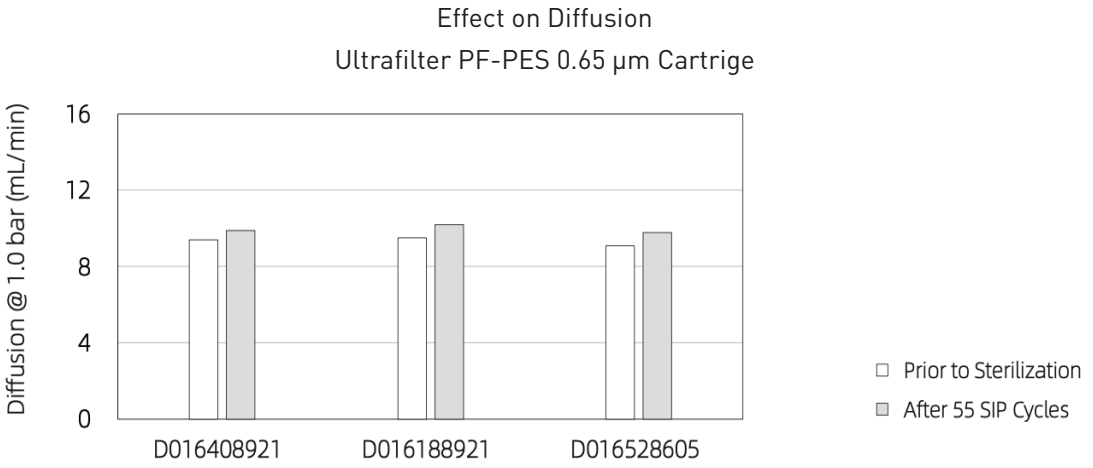
Ultrafilter PF-PES 0.45 µm Cartrige



4.1 Ultrafilter PF-PES 0.65 µm cartridge filter

LOT NUMBER	PRIOR TO STERILIZATION		AFTER 55 SIP CYCLES	
	BUBBLE POINT (BAR)	DIFFUSION @ 1.0 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 1.0 BAR (ML/MIN)
D016408921	2.114	9.4	2.034	9.9
D016188921	2.287	9.5	2.140	10.2
D016528605	2.133	9.1	1.961	11.9.8





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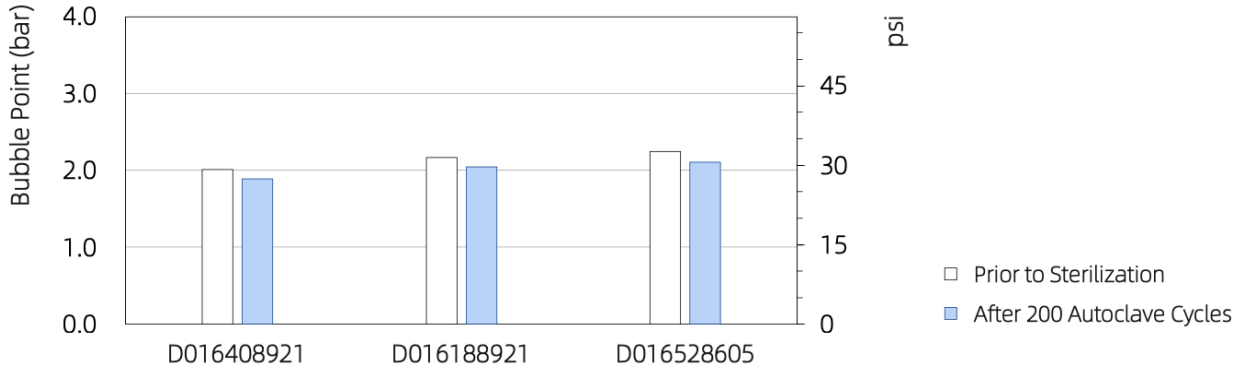
Autoclave

LOT NUMBER	PRIOR TO STERILIZATION		AFTER 200 AUTOCLAVE CYCLES	
	BUBBLE POINT (BAR)	DIFFUSION @ 1.0 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 1.0 BAR (ML/MIN)
D016408921	2.015	8.5	1.893	9.1
D016188921	2.167	10.4	2.043	11.2
D016528605	2.248	11.1	2.106	12.0

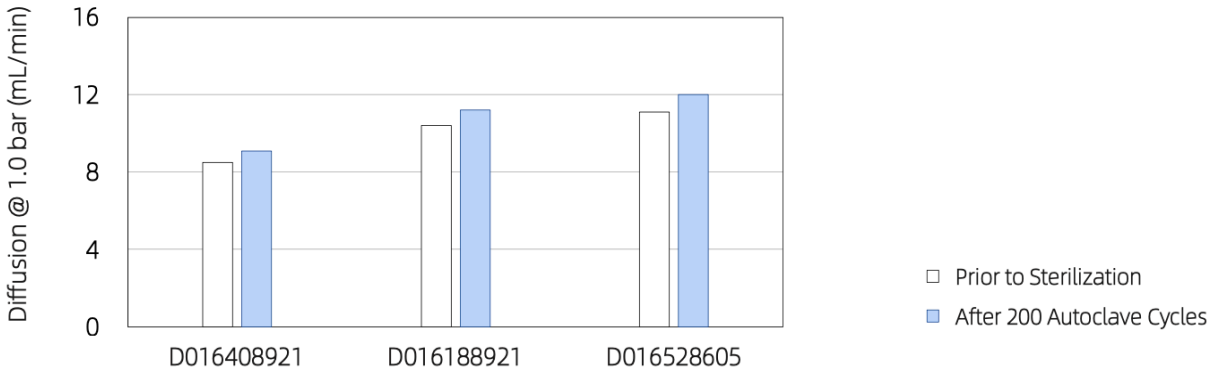
Effect on Bubble Point

Ultrafilter PF-PES 0.65 µm Cartrige



Effect on Diffusion

Ultrafilter PF-PES 0.65 µm Cartrige



Conclusion

The results indicate that the integrity of the Ultrafilter PF-PES series cartridge filters is not affected by the recommended sterilization methods.

5. Hot Water Sanitization

Ultrafilter PF-PES series cartridge filters can be hot water sanitized. Since multiple sanitization cycles may be required in actual use, the influences of the sanitization on the performances of Ultrafilter PF-PES series cartridge filters was examined. As a result, recommendations and limits for multiple sanitization are given below.

Ultrafilter PF-PES series cartridge filters were wetted with water and integrity tested prior to testing. The cartridge filters were hot water sanitized 50 cycles at 90 °C for 30 minutes at a flow rate of 800 L/h/m2. The filters were validated by integrity test to analyze and evaluate the influences of multiple sanitization.

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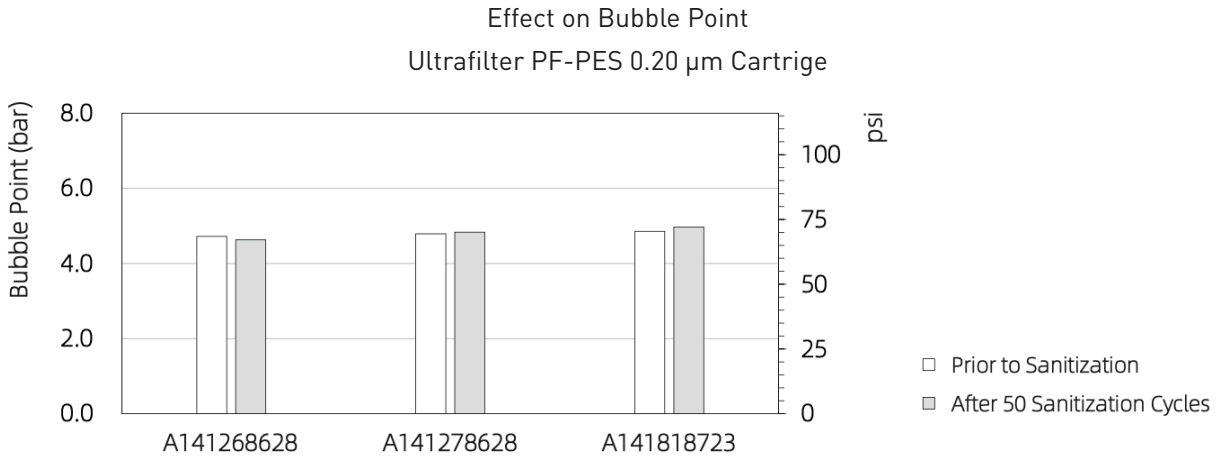
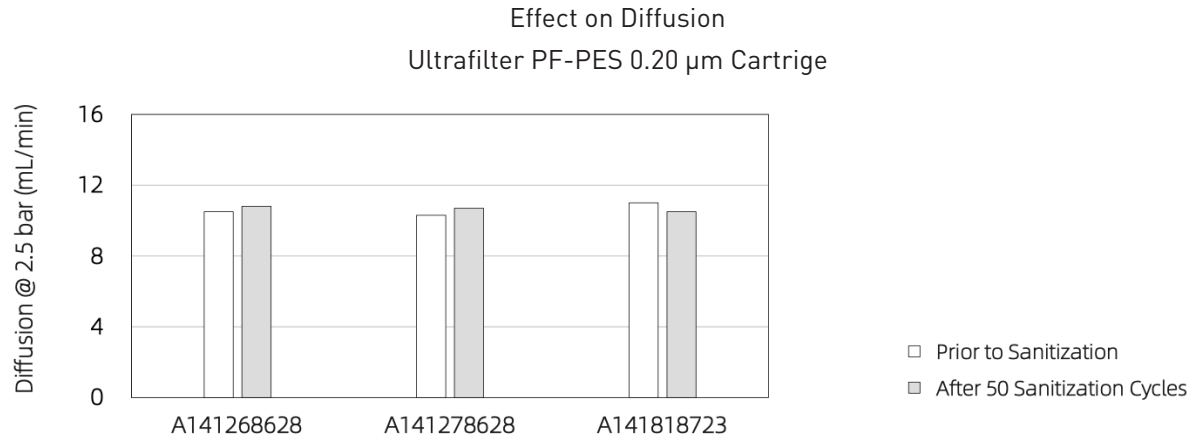
5.1 Ultrafilter PF-PES 0.20 µm cartridge filter

LOT NUMBER	PRIOR TO SANITIZATION		AFTER 50 HOT WATER SANITIZATION CYCLES	
	BUBBLE POINT (BAR)	DIFFUSION @ 2.5 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 2.5 BAR (ML/MIN)
A141268628	4.722	10.5	4.628	10.8
A141278628	4.788	10.3	4.835	10.7
A141818723	4.854	11.0	4.972	10.5



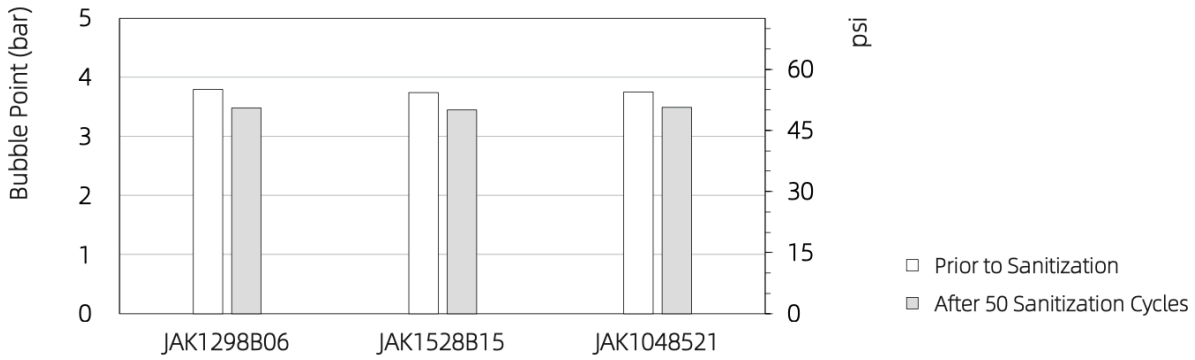


5.2 Ultrafilter PF-PES 0.45 µm cartridge filter

LOT NUMBER	PRIOR TO SANITIZATION		AFTER 50 HOT WATER SANITIZATION CYCLES	
	BUBBLE POINT (BAR)	DIFFUSION @ 1.6 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 1.6 BAR (ML/MIN)
JAK1298B06	3.797	7.3	3.484	7.9
JAK1528B15	3.742	9.3	3.446	9.7
JAK1048521	3.755	8.8	3.496	9.2

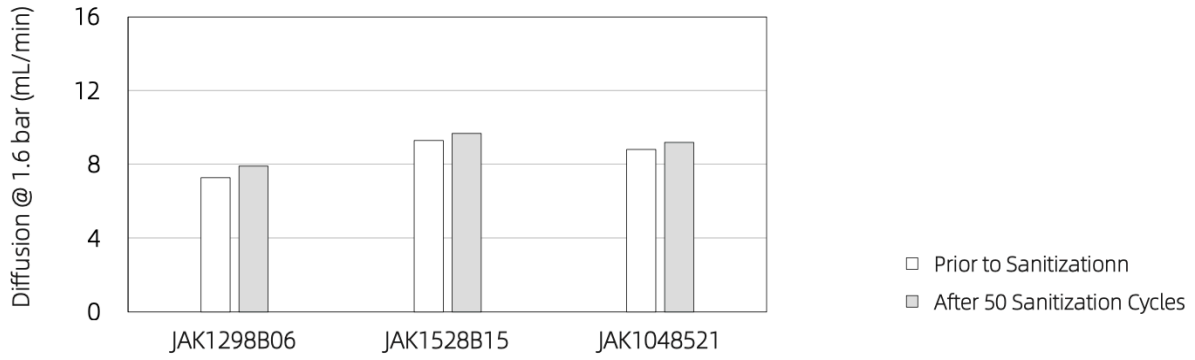
Effect on Bubble Point

Ultrafilter PF-PES 0.45 µm Cartrige



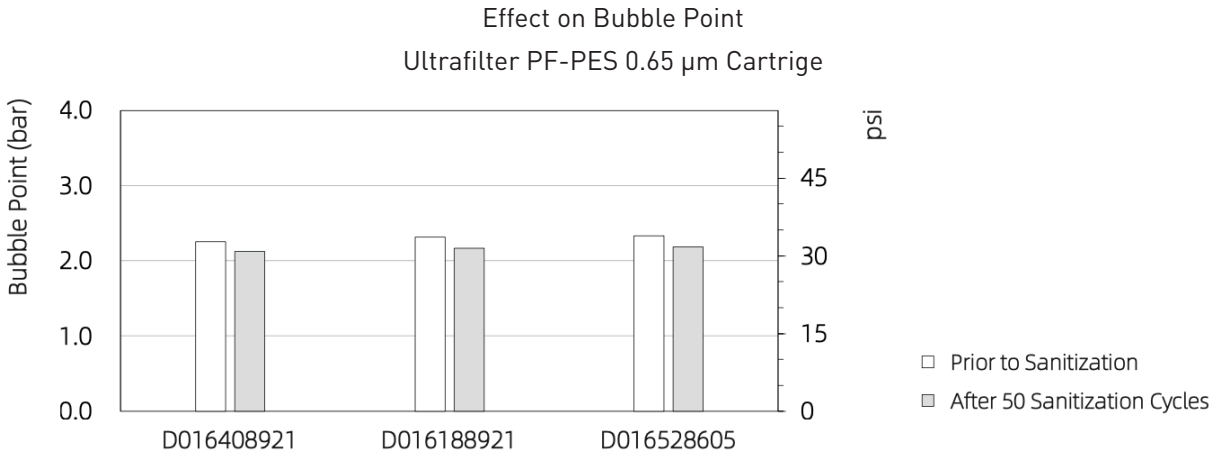
Effect on Diffusion

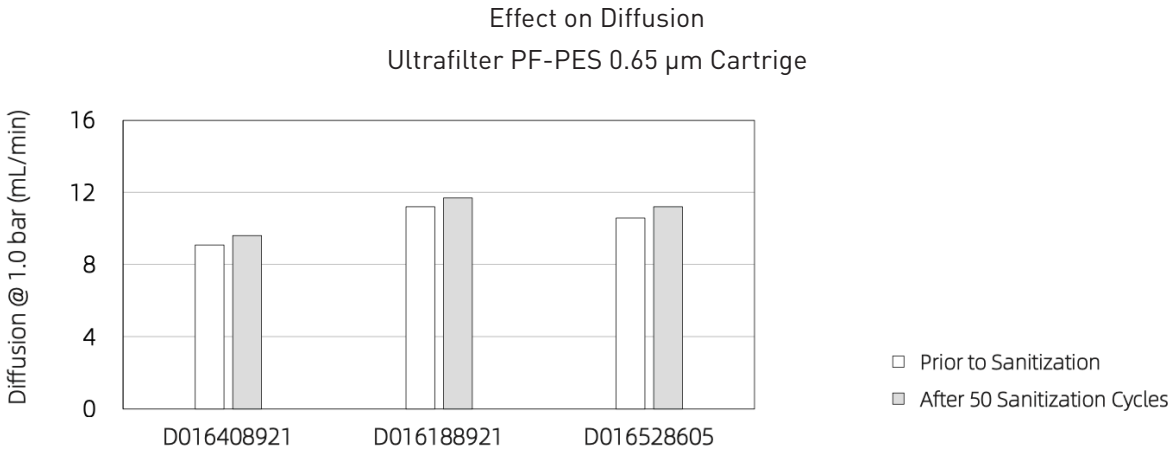
Ultrafilter PF-PES 0.45 µm Cartrige



5.3 Ultrafilter PF-PES 0.65 µm cartridge filter

LOT NUMBER	PRIOR TO SANITIZATION		AFTER 50 HOT WATER SANITIZATION CYCLES	
	BUBBLE POINT (BAR)	DIFFUSION @ 1.0 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 1.0 BAR (ML/MIN)
D016408921	2.252	9.1	2.122	9.6
D016188921	2.320	11.2	2.173	11.7
D016528605	2.337	10.6	2.190	11.2





Conclusion

The results indicate that the integrity of the Ultrafilter PF-PES series cartridge filters is not affected by the recommended sterilization methods.

6. Chemistry Sanitization

Ultrafilter PF-PES series cartridge filters can be chamistry sanitized. Since multiple sanitization cycles may be required in actual use, the influences of the sanitization on the performances of Ultrafilter PF-PES series cartridge filters was examined. As a result, recommendations and limits for multiple sanitization are given below.

Ultrafilter PF-PES series cartridge filters were wetted with water and integrity tested prior to testing. The cartridge filters were sanitized for 30 minutes at 40 °C with 50 cycles in a mix solution of sodium hypochlorite (NaClO, 100 ppm) and peroxyacetic acid (100 ppm). The filters were validated by integrity test to analyze and evaluate the influences of multiple sanitization.

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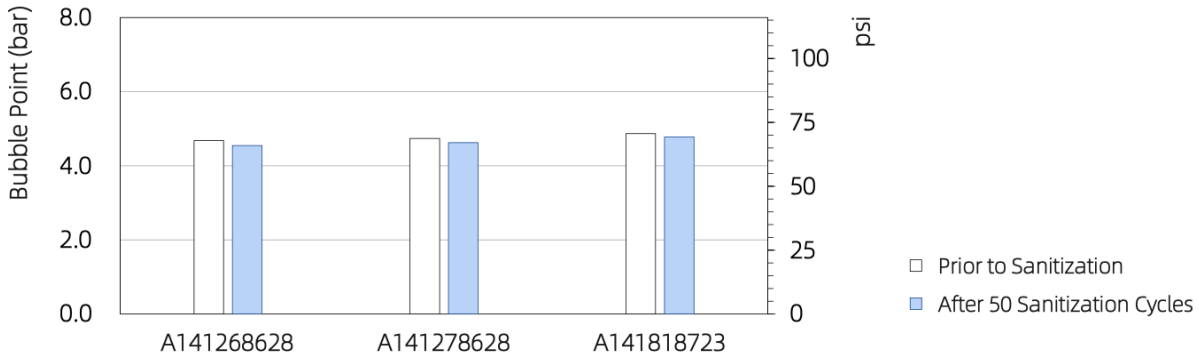
6.1 Ultrafilter PF-PES 0.20 µm cartridge filter

LOT NUMBER	PRIOR TO SANITIZATION		AFTER 50 CHEMISTRY SANITIZATION CYCLES	
	BUBBLE POINT (BAR)	DIFFUSION @ 2.5 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 2.5 BAR (ML/MIN)
A141268628	4.679	9.4	4.545	9.8
A141278628	4.736	10.1	4.626	10.6
A141818723	4.867	10.5	4.778	10.0

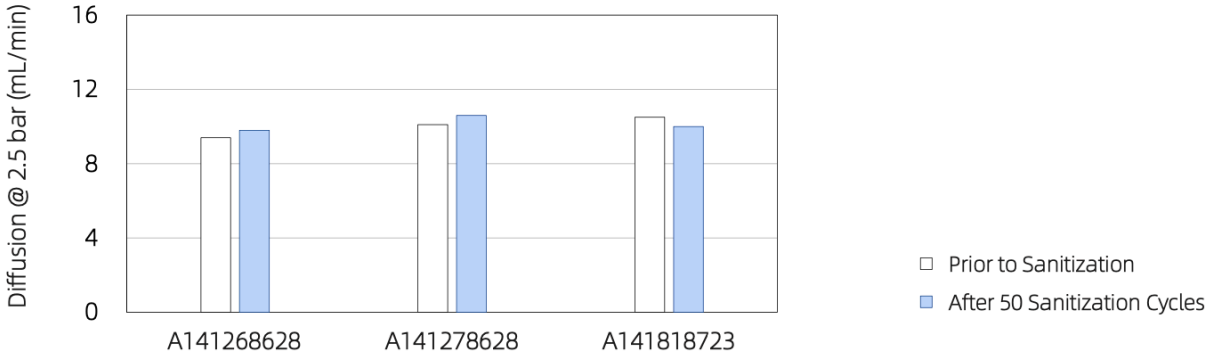
Effect on Bubble Point

Ultrafilter PF-PES 0.20 µm Cartrige



Effect on Diffusion

Ultrafilter PF-PES 0.20 µm Cartrige

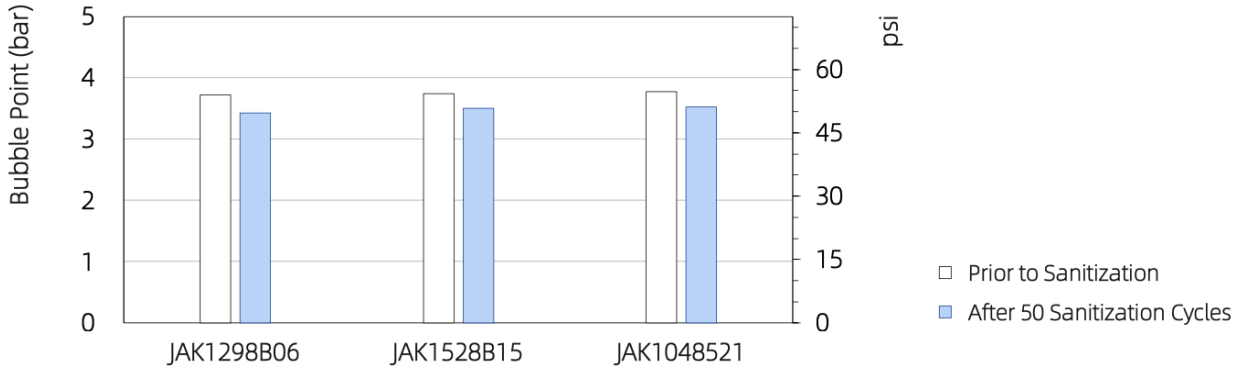


6.1 Ultrafilter PF-PES 0.45 µm cartridge filter

LOT NUMBER	PRIOR TO SANITIZATION		AFTER 50 CHEMISTRY SANITIZATION CYCLES	
	BUBBLE POINT (BAR)	DIFFUSION @ 1.6 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 1.6 BAR (ML/MIN)
JAK1298B06	3.719	9.0	3.431	9.6
JAK1528B15	3.743	9.7	3.501	10.2
JAK1048521	3.780	8.7	3.521	9.4

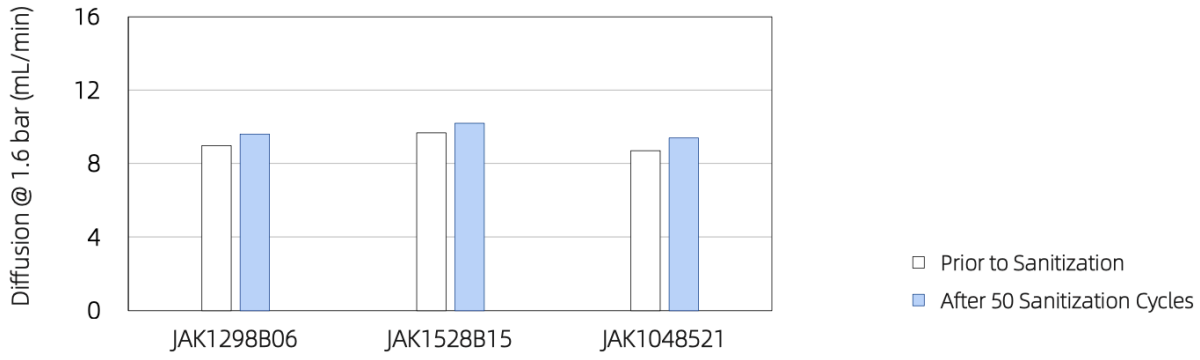
Effect on Bubble Point

Ultrafilter PF-PES 0.45 µm Cartrige



Effect on Diffusion

Ultrafilter PF-PES 0.45 µm Cartrige

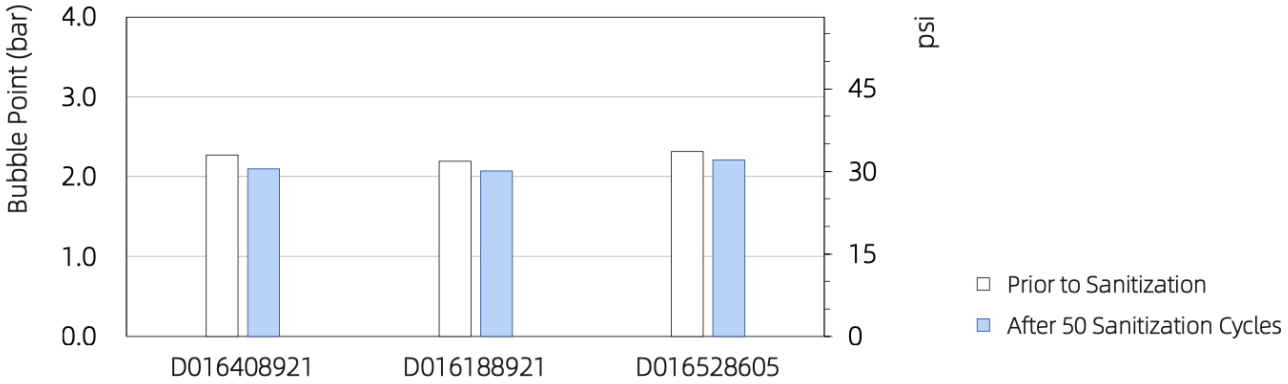


6.1 Ultrafilter PF-PES 0.65 µm cartridge filter

LOT NUMBER	PRIOR TO SANITIZATION		AFTER 50 CHEMISTRY SANITIZATION CYCLES	
	BUBBLE POINT (BAR)	DIFFUSION @ 1.0 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 1.0 BAR (ML/MIN)
D016408921	2.270	9.3	2.095	9.8
D016188921	2.192	10.5	2.075	11.3
D016528605	2.316	10.7	2.212	11.2

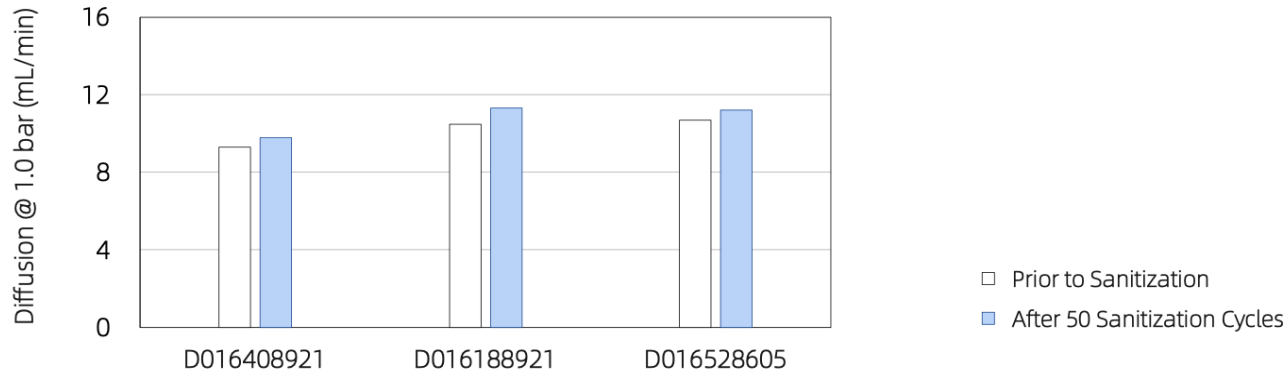
Effect on Bubble Point

Ultrafilter PF-PES 0.65 µm Cartrige



Effect on Diffusion

Ultrafilter PF-PES 0.65 µm Cartrige



Conclusion

The results indicate that the integrity of the Ultrafilter PF-PES series cartridge filters is not affected by the recommended sterilization methods.

FDA 21 CFR INDIRECT FOOD ADDITIVE

The raw materials used in manufacture Ultrafilter PF-PES series cartridge filters were confirmed to be fully compliant with the Federal Food, Drug and Cosmetic Act and applicable food additive regulations.

RESULTS

COMPONENT	MATERIALS	FDA 21 CFR REFERENCE
Membranes	Polyethersulfone	177.1520
Supports	Polypropylene	177.1520
Core, cage, end caps	Polypropylene	177.1520
O-rings	Silicone	177.2600
O-rings	EPDM	177.2600
O-rings	Fluoroelastomer	177.1550

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