ULTRAFILTER
THE FILTRATION MANUFACTURER
Kronsbein ultrafilter ®

PF-PT

Filter Cartridges | Validation Guide

ULTRAFILTER
THE FILTRATION MANUFACTURER
Kronsbein ultrafilter ®

Ultrafilter GmbH Headquarters
Otto-Hahn-Str. 1 • 40721 Hilden • Germany
Tel: +49 (0) 21 03.33 36 0 • Fax +49 (0) 21 03.33 36 36
e-Mail: info@ultra-filter.de • www.ultra-filter.de

PF-PT

CONTENT

PF-PT

ULTRAFILTER
THE FILTRATION MANUFACTURER
Kronsbein ultrafilter ®

Ultrafilter GmbH Headquarters
Otto-Hahn-Str. 1 • 40721 Hilden • Germany
Tel: +49 (0) 21 03.33 36 0 • Fax +49 (0) 21 03.33 36 36
e-Mail: info@ultra-filter.de • www.ultra-filter.de

VALIDATION GUIDE

INTRODUCTION

Ultrafilter PF-PT cartridge Cartridge filter contains a hydrophobic polytetrafluoroethylene (PTFE) membrane, which has a Brevundimonas diminuta (ATCC® 19146) removal rating of 0.2 µm in liquids and a particulate removal rating of 0.01 µm in gases. Ultrafilter PF-PT cartridge filter is designed for sterile filtration in food and beverage industry. The purpose of this report is to summarize tests done to qualify the performance of Ultrafilter PF-PT cartridge filter 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 and cGMP. All the products are manufactured under a 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 the 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 the 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.

Ultrafilter GmbH Headquarters
Otto-Hahn-Str. 1 • 40721 Hilden • Germany
Tel: +49 (0) 21 03.33 36 0 • Fax +49 (0) 21 03.33 36 36
e-Mail: info@ultra-filter.de • www.ultra-filter.de

PF-PT

PRODUCT SPECIFICATIONS

CATALOGUE NUMBERS DESCRIPTION

PF-PT-F (for liquids) **PF-PT-G** (for gas)

	PORE SIZE	FILTER LENGTH	CARTRIDGE ADAPTER TYPE	SEAL MATERIAL	PHARMA GRADE
	10= 0.1 µm	05 = 5"	UF = UF Plug	A = EPDM	-V
	20= 0.2 µm	10 = 10"	M = DOE	B = Silicone	
	45= 0.45 µm	20 = 20"	2 = P2	C = Viton	
		30 = 30"	3 = P3	D= Nitrile	
		40 = 40"	7 = P7	E = FEP Viton	
			8 = P8	F = FEP Silicone	
			9 = P9		

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

ULTRAFILTER
THE FILTRATION MANUFACTURER
Kronsbein ultrafilter ®

Ultrafilter GmbH Headquarters
Otto-Hahn-Str. 1 • 40721 Hilden • Germany
Tel: +49 (0) 21 03.33 36 0 • Fax +49 (0) 21 03.33 36 36
e-Mail: info@ultra-filter.de • www.ultra-filter.de

VALIDATION GUIDE

SPECIFICATIONS

FILTER	PF-PT
MATERIALS OF CONSTRUCTION	
FILTER MEMBRANE	HYDROPHOBIC POLYTETRAFLUOROETHYLENE (PTFE)
SUPPORTS	POLYPROPYLENE
CORE, CAGE, END CAPS	POLYPROPYLENE
ADAPTER INTERNAL SUPPORT	STAINLESS STEEL 316L
O-RINGS	SILICONE, EPDM, FLUOROELASTOMER
PORE SIZE	
IN LIQUIDS	0.2 µm
IN GASES	0.01 µm
EFFECTIVE FILTRATION AREA	0.85 M2 (9.1 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
BUBBLE POINT AT 20 °C	≥ 1.1 BAR (16 PSI) IN 60% ISOPROPANOL (IPA) 40% WATER, AIR
AIR DIFFUSION AT 20 °C	≤ 16 ML/MIN AT 0.8 BAR (11.6 PSI), 60% ISOPROPANOL (IPA) 40% WATER WETTED
WATER INTRUSION AT 20 °C	≤ 0.38 ML/MIN AT 2.5 BAR (36 PSI)
BACTERIAL RETENTION	RETENTION OF 107 CFU/CM2 BREVUNDIMONAS DIMINUTA (ATCC® 19146) ACCORDING TO ASTM F838.
STERILIZATION	
STEAM IN PLACE	CAN BE STEAM STERILIZED FOR 30 MINUTES AT 145 °C (< 0.3 BAR, 5 PSI) IN FORWARD DIRECTION WITH 100 CYCLES AND IN REVERSE DIRECTION (< 0.1 BAR, 1.5 PSI) WITH 50 CYCLES.
AUTOCLAVE	CAN BE AUTOCLAVED 400 CYCLES FOR 30 MINUTES AT 130 °C.
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.

ULTRAFILTER
THE FILTRATION MANUFACTURER
Kronsbein ultrafilter ®

Ultrafilter GmbH Headquarters
Otto-Hahn-Str. 1 • 40721 Hilden • Germany
Tel: +49 (0) 21 03.33 36 0 • Fax +49 (0) 21 03.33 36 36
e-Mail: info@ultra-filter.de • www.ultra-filter.de

PERFORMANCE VERIFICATION

1. Bacteria Challenge Test (BCT)

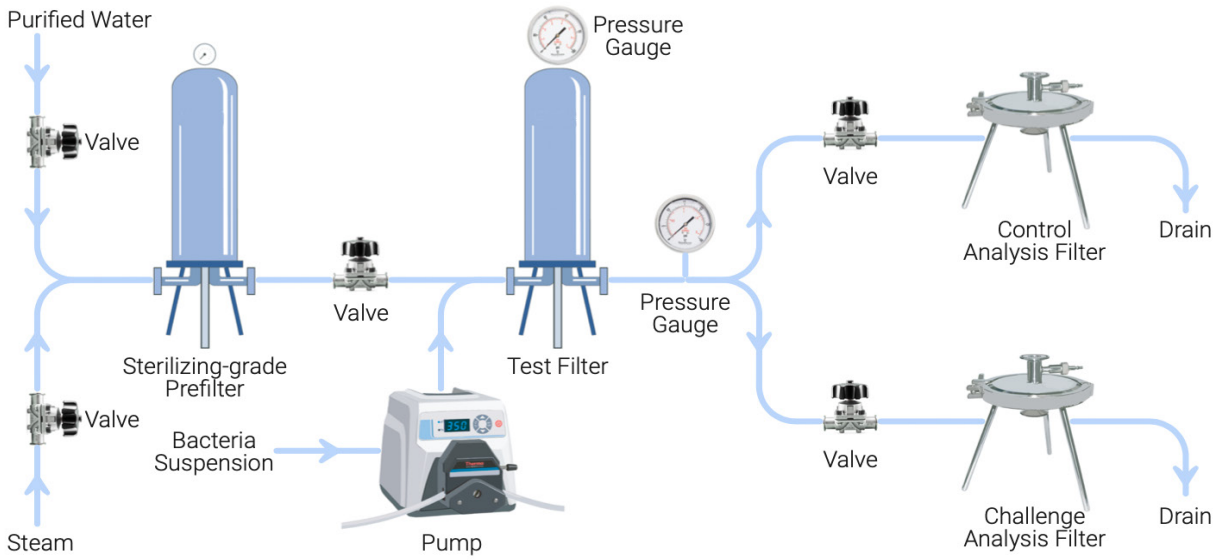
A liquid bacteria challenge test (BCT) was performed to confirm that Ultrafilter PF-PT cartridge filter can completely retain a minimum concentration of 107 cfu/cm^2 Brevundimonas diminuta (ATCC® 19146) and meet the criteria for sterilizing grade performance as defined in ASTM methodology.

Summary of Method

Ultrafilter PF-PT cartridge filters were tested with water intrusion at a pressure of 2.5 bar and steamed at 145 °C for 30 minutes prior to testing. The cartridge filters wetted with 60% isopropanol (IPA) 40% water were subjected to integrity test and then challenged with Brevundimonas diminuta (ATCC® 19146) of the challenge level over 1×107 cfu/cm^2 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.

Bacterial Challenge Test Schematic



VALIDATION GUIDE

LOT NUMBER	WATER INTRUSION @ 2.5 bar (mL/min)	CHALLENGE LEVEL (cfu/unit)	FILTRATE STERILITY	LRV/CM²
YCJ9188914	0.18	1.44×10^{11}	Sterile	7.23
YCJ9268A10	0,19	2.64×10^{11}	Sterile	7.49
YDN5348A23	0.20	2.23×10^{11}	Sterile	7.42
YDN5118A26	0.20	1.78×10^{11}	Sterile	7.32
YDN5188A26	0.20	1.78×10^{11}	Sterile	7.32
YE68148B15	0.22	2.23×10^{11}	Sterile	7.42
YEG8268B23	0.23	1.05×10^{11}	Sterile	7.09
YEG8038B23	0.23	2.05×10^{11}	Sterile	7.38
YFL4098C26	0.23	2.64×10^{11}	Sterile	7.49
YFL4048C26	0.24	1.10×10^{11}	Sterile	7.11
YV28048222	0.24	1.26×10^{11}	Sterile	7.17
YV28338306	0.25	1.62×10^{11}	Sterile	7.28

Conclusion

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

ULTRAFILTER
THE FILTRATION MANUFACTURER
Kronsbein ultrafilter ®

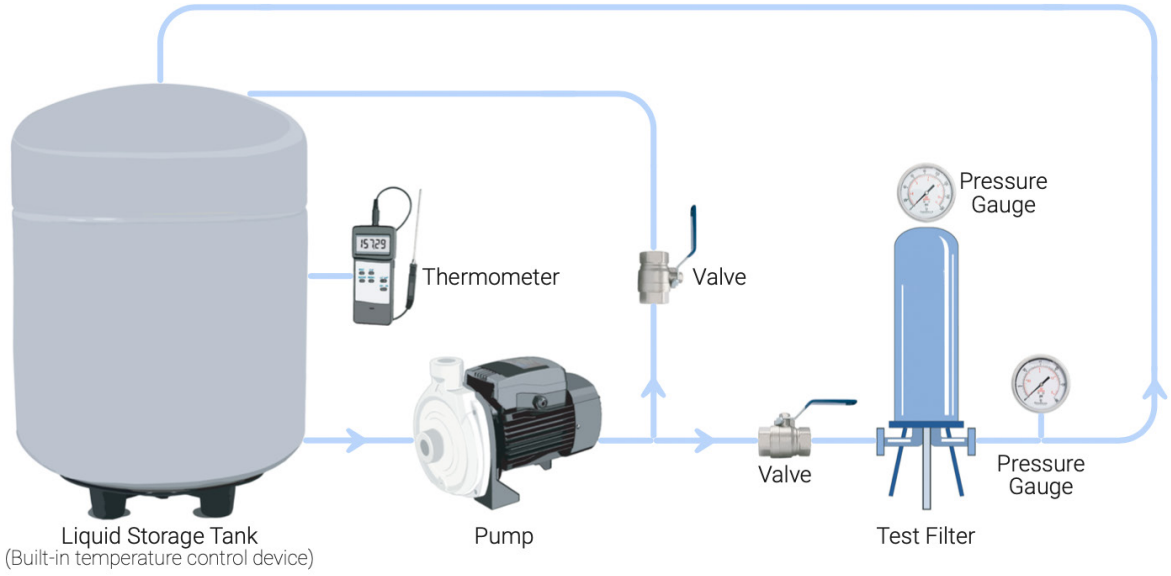
Ultrafilter GmbH Headquarters
Otto-Hahn-Str. 1 • 40721 Hilden • Germany
Tel: +49 (0) 21 03.33 36 0 • Fax +49 (0) 21 03.33 36 36
e-Mail: info@ultra-filter.de • www.ultra-filter.de

PERFORMANCE VERIFICATION

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.

Bacterial Challenge Test Schematic



2.1. Hydraulic Stress Test at 25 °C

Summary of Method

Ultrafilter PF-PT cartridge filters were steamed at 145 °C for 30 minutes prior to testing. The filters were wetted with 60% isopropanol (IPA) 40% 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 in the process of the hydraulic stress tests.

Results

	PRIOR TO HYDRAULIC STRESS		POST HYDRAULIC STRESS	
LOT NUMBER	**BUBBLE POINT** (BAR)	**DIFFUSION @ 0.8** BAR (ML/MIN)	**BUBBLE POINT** (BAR)	**DIFFUSION @ 0.8 BAR** (ML/MIN)
YDN5118A26	1.693	8.5	1.632	8.5
YAM6068730	1.681	9.5	1.700	9.6
YCJ9368830	1.506	8.5	1.458	8.6

Conclusion

Ultrafilter PF-PT cartridge filter maintains integrity after a series of hydraulic stress tests at 25 °C described above.

Ultrafilter GmbH Headquarters
Otto-Hahn-Str. 1 • 40721 Hilden • Germany
Tel: +49 (0) 21 03.33 36 0 • Fax +49 (0) 21 03.33 36 36
e-Mail: info@ultra-filter.de • www.ultra-filter.de

2.2. Hydraulic Stress Test at 80 °C

Summary of Method

Ultrafilter PF-PT cartridge filters were steamed at 145 °C for 30 minutes prior to testing. The filters were wetted with 60% isopropanol (IPA) 40% 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 the reverse direction with 3 cycles.

The filter integrity test was carried out to find any changes in the process of the hydraulic stress tests.

LOT NUMBER	PRIOR TO HYDRAULIC STRESS		POST HYDRAULIC STRESS	
	BUBBLE POINT (BAR)	DIFFUSION @ 0.8 BAR (ML/MIN)	BUBBLE POINT (BAR)	DIFFUSION @ 0.8 BAR (ML/MIN)
YDN5118A26	1.625	9.0	1.679	8.7
YAM6068730	1.591	10.1	1.576	10.1
YCJ9368830	1.549	9.4	1.596	9.7

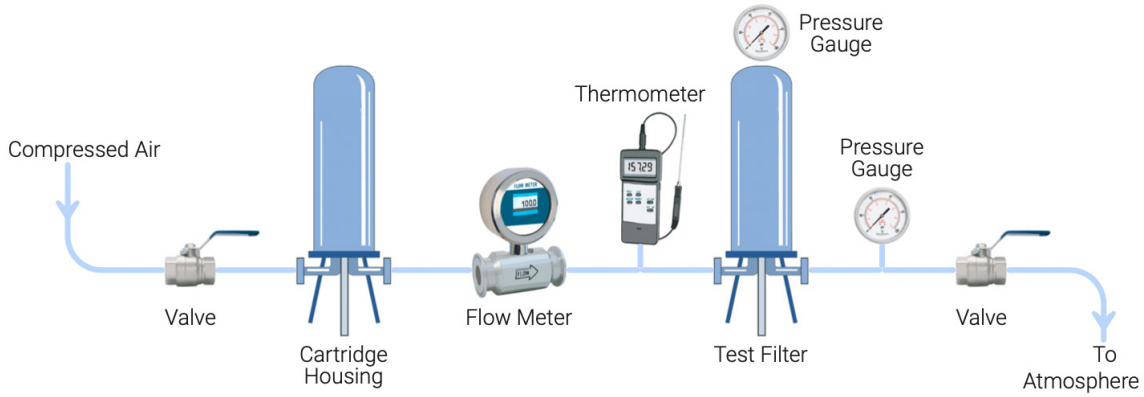
Conclusion

Ultrafilter PF-PT cartridge filter maintains integrity after a series of hydraulic stress tests at 80 °C described above.

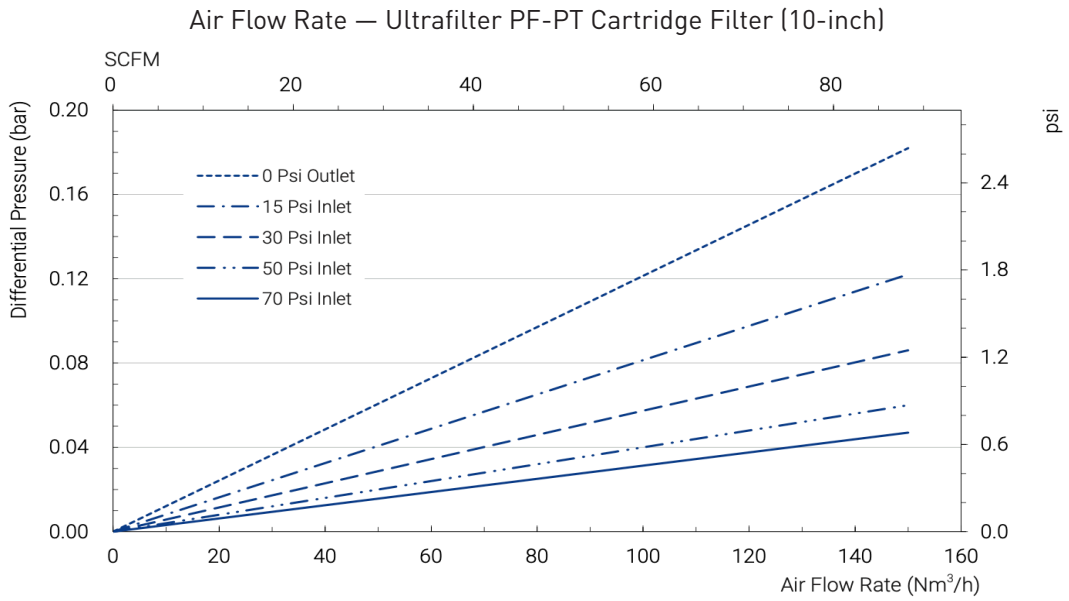
3. Air Flow Rate

Ultrafilter PF-PT cartridge filters were steamed at 145 °C for 30 minutes, and then dried prior to testing. The filters were installed into the air flow test device. After achieving a constant differential pressure, the flow rate is recorded from the flow meter. Upstream air temperature was maintained at 20 °C.

Air Flow Rate Test Schematic



Results

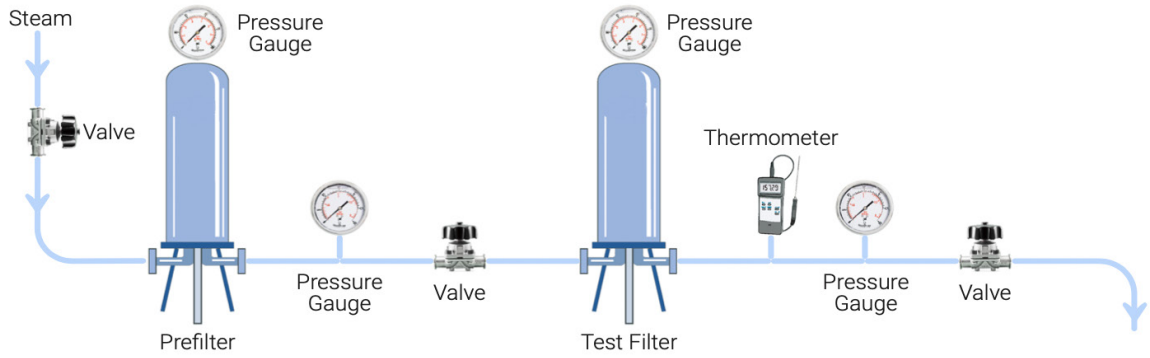


THERMAL RESISTANCE

Ultrafilter PF-PT cartridge filter 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-PT cartridge filter were examined. As a result, recommendations and limits for multiple sterilization are given below.

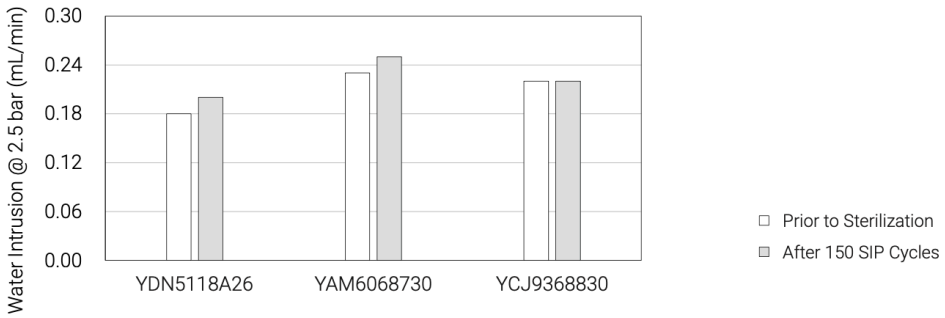
Ultrafilter PF-PT cartridge filters were integrity tested and autoclaved 400 cycles at 130 °C for 30 minutes, or the filters were steam sterilized at 145 °C for 30 minutes in the forward direction with 100 cycles under a differential pressure of less than 0.3 bar and in the reverse direction with 50 cycles under a differential pressure of less than 0.1 bar. The filters were validated by integrity test to analyze and evaluate the influences of multiple sterilization.

Schematic of Steam-in-Place

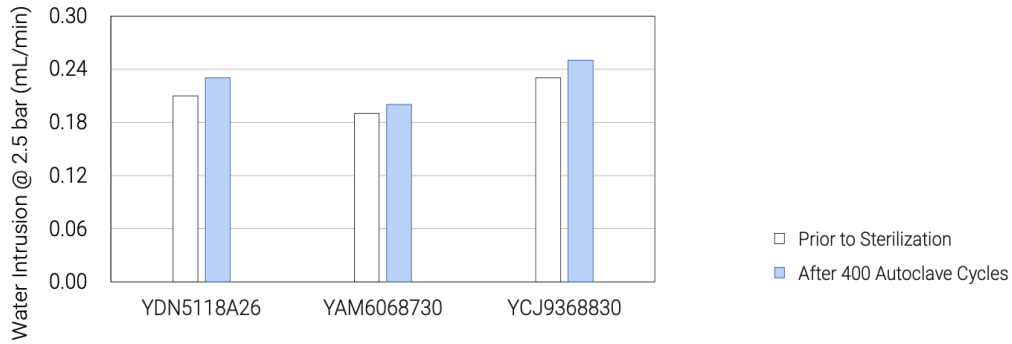


Results

LOT NUMBER	WATER INTRUSION @ 2.5 BAR (ML/MIN)	
	PRIOR TO STERILIZATION	AFTER MULTIPLE STEAM CYCLES
YDN5118A26	0.18	0.20
YAM6068730	0.23	0.25
YCJ9368830	0.22	0.22
AFTER 400 AUTOCLAVE CYCLES		
YDN5118A26	0.21	0.23
YAM6068730	0.19	0.20
YCJ9368830	0.23	0.25



Effect on Water Intrusion - Ultrafilter PF-PT



Conclusion

The results indicate that the integrity of the Ultrafilter PF-PT cartridge filter is not affected by the recommended sterilization methods.

ULTRAFILTER
THE FILTRATION MANUFACTURER
Kronsbein ultrafilter ®

Ultrafilter GmbH Headquarters
Otto-Hahn-Str. 1 • 40721 Hilden • Germany
Tel: +49 (0) 21 03.33 36 0 • Fax +49 (0) 21 03.33 36 36
e-Mail: info@ultra-filter.de • www.ultra-filter.de

FDA 21 CFR INDIRECT FOOD ADDITIVE

The raw materials used to manufacture Ultrafilter PF-PT 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	Polytetrafluoroethylene	177.1550
Supports	Polypropylene	177.1520
Core, cage, end caps	Polypropylene	177.1520
O-rings	Silicone	177.2600
O-rings	EPDM	177.2600
O-rings	FEP/PFA encapsulated Fluoroelastomer	177.1550

ULTRAFILTER
THE FILTRATION MANUFACTURER
Kronsbein ultrafilter ®

Ultrafilter GmbH Headquarters
Otto-Hahn-Str. 1 • 40721 Hilden • Germany
Tel: +49 (0) 21 03.33 36 0 • Fax +49 (0) 21 03.33 36 36
e-Mail: info@ultra-filter.de • www.ultra-filter.de

ULTRAFILTER
THE FILTRATION MANUFACTURER

Kronsbein ultrafilter ®

Hersteller / Manufacturer
ultrafilter GmbH Headquaters
Otto-Hahn-Strasse 1
40721 Hilden
Germany

eMail info@ultrafilter.ch
www.ultrafilter.ch

Vertrieb / *Sales*
Schweiz / Switzerland

ultrafilter ag
Leutschenbachstrasse 45
CH-8050 Zürich

Fon: +41 (0)44 224 60 60
Fax: +41 (0)44 224 60 61

eMail: info@ultrafilter.ch
www.ultrafilter.ch