ULTRAFILTER
THE FILTRATION MANUFACTURER

Kronsbein ultrafilter ®

PF-PP

Filter Cartridges | Validation Guide

ULTRAFILTER
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Ultrafilter GmbH Headquarters

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PF-PP

CONTENT

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VALIDATION GUIDE

INTRODUCTION

Ultrafilter PF-PP series cartridge filters contain 0.2 µm, 0.3 µm, 0.5 µm, 0.65 µm, 0.8 µm, 1.0 µm, 3.0 µm, 5.0 µm, 6.0 µm or 10 µm polypropylene (PP) membrane, which are designed for different filtration in food and beverage industry. The purpose of this report is to summarize tests done to qualify the performance of Ultrafilter PF-PP 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-PP

PRODUCT SPECIFICATIONS

CATALOGUE NUMBERS DESCRIPTION					
PF-PP					
	PORE SIZE	**FILTER LENGTH**	**CARTRIDGE ADAPTER TYPE**	**SEAL MATERIAL**	**PHARMA GRADE**
	20 = 0.2 µm	05 = 5"	2 = Code 2	A = EPDM	-V
	30 = 0.3 µm	10 = 10"	3 = Code 3	B = Silicone	
	50 = 0.5 µm	20 = 20"	7 = Code 7	C = Viton	
	65 = 0.65 µm	30 = 30"	8 = Code 8	D= Nitrile	
	80 = 0.8 µm	40 = 40"	MF = DOE	E = FEP Viton	
	100 = 1.0 µm		UF = UF	F = FEP Silicone	
	300 = 3.0 µm				
	500 = 5.0 µm				
	600 = 6.0 µm				
	1000 = 10.0 µm				

Example Part Number:	**Filter-Type**	**Pore size**	**Filter Lenght**	**Connection Type**	**Sealing**	**Pharma Grade**
	PF-PP	20	30	7	-B	-V

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VALIDATION GUIDE

SPECIFICATIONS			
FILTER	**PF-PP 0.2 µm**	**PF-PP 0.3 µm**	**PF-PP 0.5 µm**
LENGTH	254.0 MM (10 INCH)		
DIAMETER	71.0 MM (2.8 INCH)		
MATERIALS OF CONSTRUCTION			
FILTER MEMBRANE	POLYPROPYLENE (PP)		
SUPPORTS	POLYPROPYLENE		
CORE, CAGE, END CAPS	POLYPROPYLENE		
ADAPTER INTERNAL SUPPORT	STAINLESS STEEL 316L		
O-RINGS	SILICONE, EPDM		
PORE SIZE	0.2 µm	0.3 µm	0.5 µm
EFFECTIVE FILTRATION AREA	0.55 M² (5.9 FT²)	0.44 m² (4.7 ft²)	0.44 m² (4.7 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		
STERILIZATION			
STEAM IN PLACE	CAN BE STEAM STERILIZED 20 CYCLES FOR 30 MINUTES AT 125 °C (< 0.3 BAR, 5 PSI).		
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 THE 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-PP

SPECIFICATIONS			
FILTER	**PF-PP 0.65 µm**	**PF-PP 0.8 µm**	**PF-PP 1.0 µm**
LENGTH	254.0 MM (10 INCH)		
DIAMETER	71.0 MM (2.8 INCH)		
MATERIALS OF CONSTRUCTION			
FILTER MEMBRANE	POLYPROPYLENE (PP)		
SUPPORTS	POLYPROPYLENE		
CORE, CAGE, END CAPS	POLYPROPYLENE		
ADAPTER INTERNAL SUPPORT	STAINLESS STEEL 316L		
O-RINGS	SILICONE, EPDM		
PORE SIZE	0.65 µm	0.8 µm	1.0 µm
EFFECTIVE FILTRATION AREA	0.60 M^2 (6.5 FT^2)	0.62 m^2 (6.7 ft^2)	0.60 m^2 (6.5 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		
STERILIZATION			
STEAM IN PLACE	CAN BE STEAM STERILIZED 20 CYCLES FOR 30 MINUTES AT 125 °C (< 0.3 BAR, 5 PSI).		
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 THE MIXED SOLUTION OF SODIUM HYPOCHLORITE (NACLO, 100 PPM) AND PEROXYACETIC ACID (100 PPM).		
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SPECIFICATIONS			
FILTER	**PF-PP 3.0 µm**	**PF-PP 5.0 µm**	**PF-PP 6.0 µm**
LENGTH	254.0 MM (10 INCH)		
DIAMETER	71.0 MM (2.8 INCH)		
MATERIALS OF CONSTRUCTION			
FILTER MEMBRANE	POLYPROPYLENE (PP)		
SUPPORTS	POLYPROPYLENE		
CORE, CAGE, END CAPS	POLYPROPYLENE		
ADAPTER INTERNAL SUPPORT	STAINLESS STEEL 316L		
O-RINGS	SILICONE, EPDM		
PORE SIZE	3.0 µm	5.0 µm	6.0 µm
EFFECTIVE FILTRATION AREA	0.60 M² (6.5 FT²)	0.65 m² (7.0 ft²)	0.44 m² (4.7 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		
STERILIZATION			
STEAM IN PLACE	CAN BE STEAM STERILIZED 20 CYCLES FOR 30 MINUTES AT 125 °C (< 0.3 BAR, 5 PSI).		
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 THE 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.		
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PF-PP

SPECIFICATIONS	
FILTER	**PF-PP 10.0 µm**
LENGTH	254.0 MM (10 INCH)
DIAMETER	71.0 MM (2.8 INCH)
MATERIALS OF CONSTRUCTION	
FILTER MEMBRANE	POLYPROPYLENE (PP)
SUPPORTS	POLYPROPYLENE
CORE, CAGE, END CAPS	POLYPROPYLENE
ADAPTER INTERNAL SUPPORT	STAINLESS STEEL 316L
O-RINGS	SILICONE, EPDM
PORE SIZE	10.0 µm
EFFECTIVE FILTRATION AREA	0.69 M^2 (7.4 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
STERILIZATION	
STEAM IN PLACE	CAN BE STEAM STERILIZED 20 CYCLES FOR 30 MINUTES AT 125 °C (< 0.3 BAR, 5 PSI).
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 THE 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.
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PERFORMANCE VERIFICATION

1. Particle Retention

Summary of Method

µUltrafilter PF-PP series cartridge filters were steamed at 125 °C for 30 minutes prior to testing. Ultrafilter PF-PP series cartridge filters were wetted with isopropanol (IPA) solution and installed in test system. The test devices and connected tubing were pre-flushed until the system condition meets the testing requirements. The 5 mg/L analytical suspension made of the mixture of ISO12103-1 A4 standard particles and purified water was filtered through the tested cartridge filters. The amount of particles is measured upstream and downstream by the particle counter, and then particle retention rate was calculated using the following formula:

$$\text{PARTICAL RETENTION RATE RX} = \left[1 - \frac{\text{PARTICLES}_{\text{DOWNSTREAM}}}{\text{PARTICLES}_{\text{UPSTREAM}}}\right] \times 100\%$$

Partical Retention Specifications

FILTER TYPE	RETENTION RATES OF EACH PARTICAL SIZE (%)							
	1.0 µm	3.0 µm	4.0 µm	5.0 µm	6.0 µm	7.0 µm	10.0 µm	20.0 µm
PF-PP 0.2 µm	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99
PF-PP 0.3 µm	≥ 99.98	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99
PF-PP 0.5 µm	≥ 99.90	≥ 99.98	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99
PF-PP 0.65 µm	≥ 99.50	≥ 99.90	≥ 99.98	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99
PF-PP 0.8 µm	≥ 99.20	≥ 99.50	≥ 99.90	≥ 99.98	≥ 99.99	≥ 99.99	≥ 99.99	≥ 99.99
PF-PP 1.0 µm	≥ 99.00	≥ 99.20	≥ 99.50	≥ 99.90	≥ 99.98	≥ 99.99	≥ 99.99	≥ 99.99
PF-PP 3.0 µm		≥ 99.00	≥ 99.20	≥ 99.50	≥ 99.90	≥ 99.98	≥ 99.99	≥ 99.99
PF-PP 5.0 µm				≥ 99.00	≥ 99.20	≥ 99.50	≥ 99.90	≥ 99.98
PF-PP 6.0 µm					≥ 99.00	≥ 99.20	≥ 99.50	≥ 99.90
PF-PP 10.0 µm							≥ 99.20	≥ 99.20

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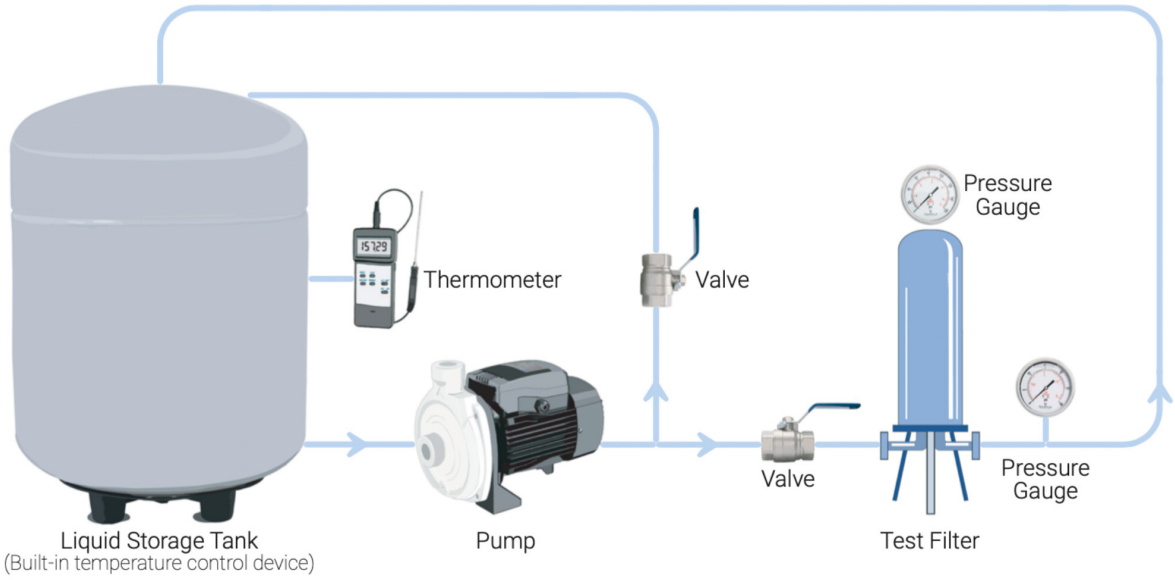
2. Hydraulic Stress

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 structural 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-PP 0.2 µm cartridge filters were steamed at 125 °C for 30 minutes prior to testing 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.

Ultrafilter PF-PP 0.2 µm cartridge filter

	FILTER INTEGRITY	
LOT NUMBER	PRIOR TO HYDRAULIC STRESS	POST HYDRAULIC STRESS
B140679627	Integral	Integral
B140699627	Integral	Integral
B140719627	Integral	Integral

Conclusion

Ultrafilter PF-PP 0.2 µm cartridge filter maintains 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-PP 0.2 µm cartridge filters were steamed at 125 °C for 30 minutes prior to testing 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 during the hydraulic stress test.

Ultrafilter PF-PP 0.2 µm cartridge filter

	FILTER INTEGRITY	
LOT NUMBER	PRIOR TO HYDRAULIC STRESS	POST HYDRAULIC STRESS
B140679627	Integral	Integral
B140699627	Integral	Integral
B140719627	Integral	Integral

Conclusion

Ultrafilter PF-PP 0.2 µm cartridge filter maintains integrity after a series of hydraulic stress tests at 80 °C described above.

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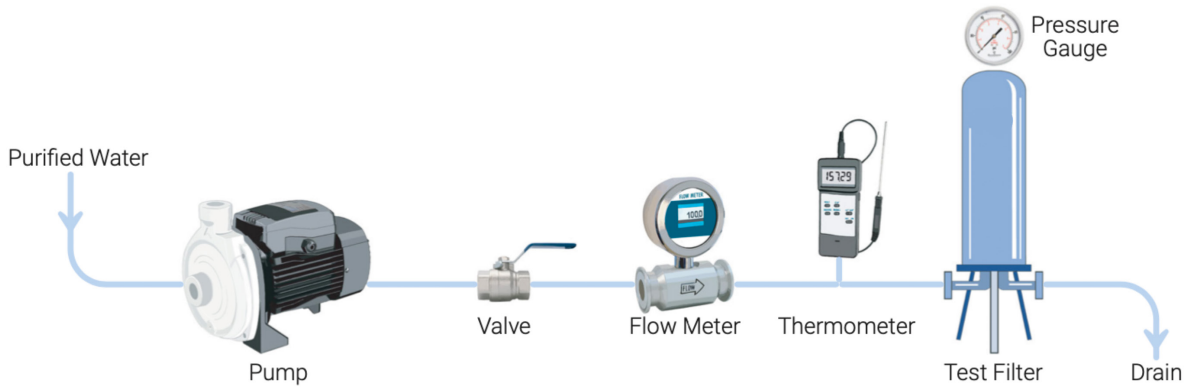
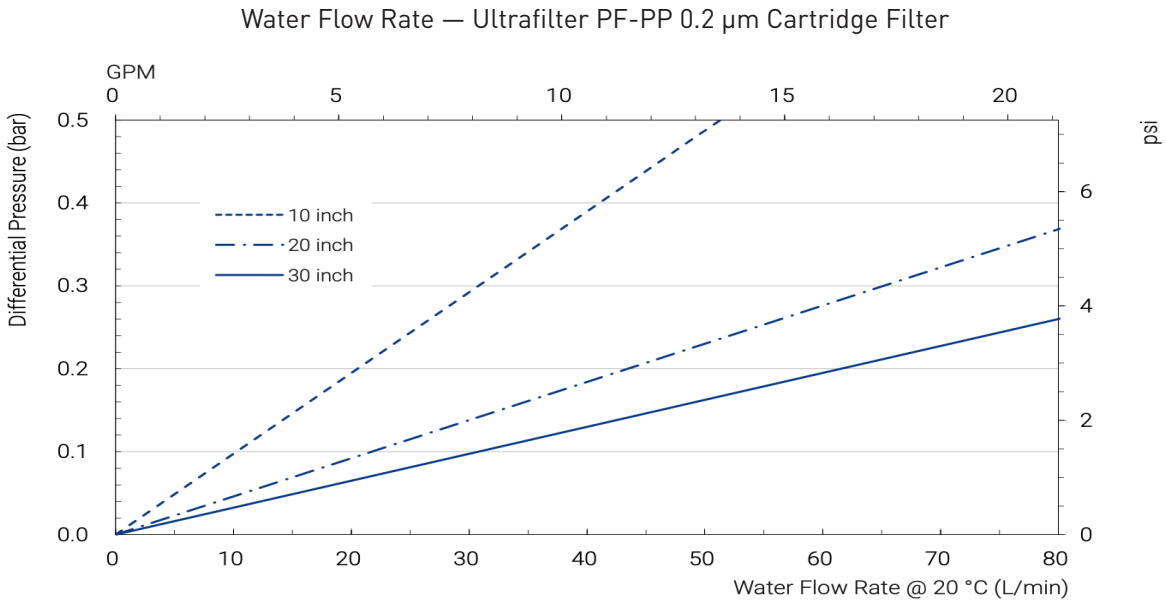
3. Water Flow Rate

Ultrafilter PF-PP series cartridge filters were steamed at 125 °C for 30 minutes prior to testing and then integrity tested. 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 temperature were recorded. All the results of filters were corrected to a water temperature of 20 °C.

Water Flow Rate Test Schematic

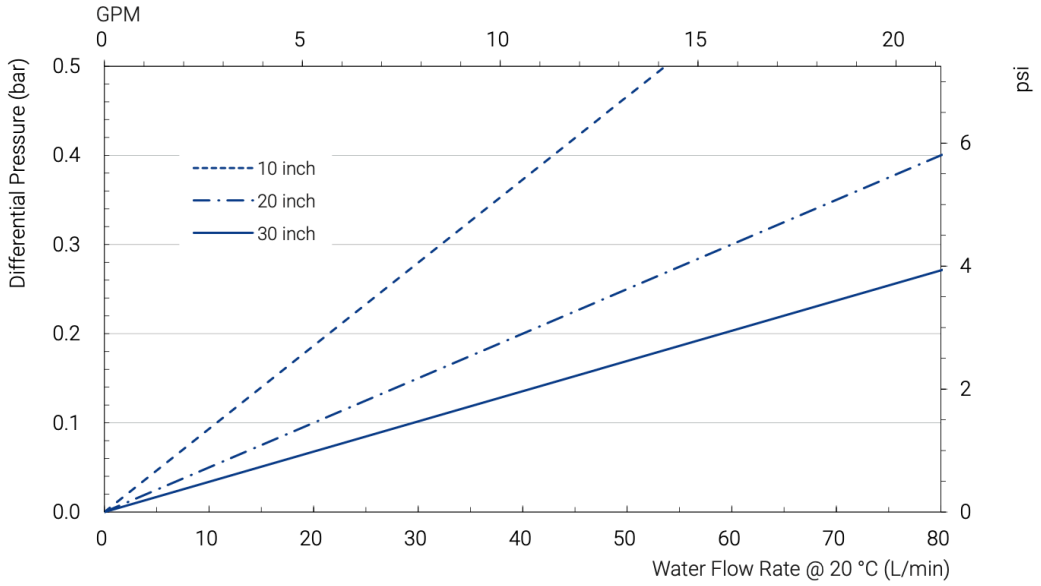


Results

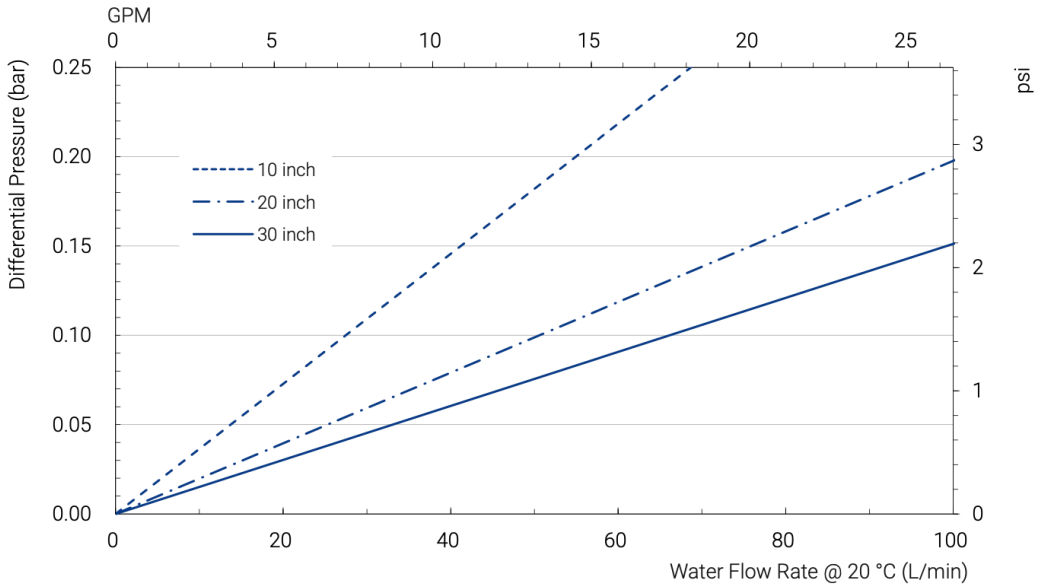


PF-PP

Water Flow Rate — Ultrafilter PF-PP 0.3 µm Cartridge Filter



Water Flow Rate — Ultrafilter PF-PP 0.5 µm Cartridge Filter



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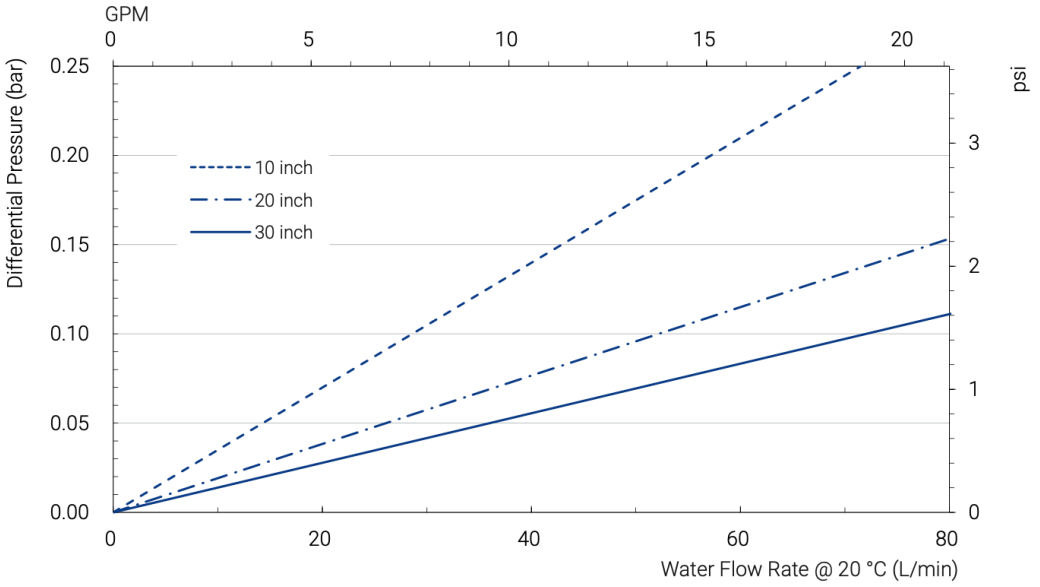
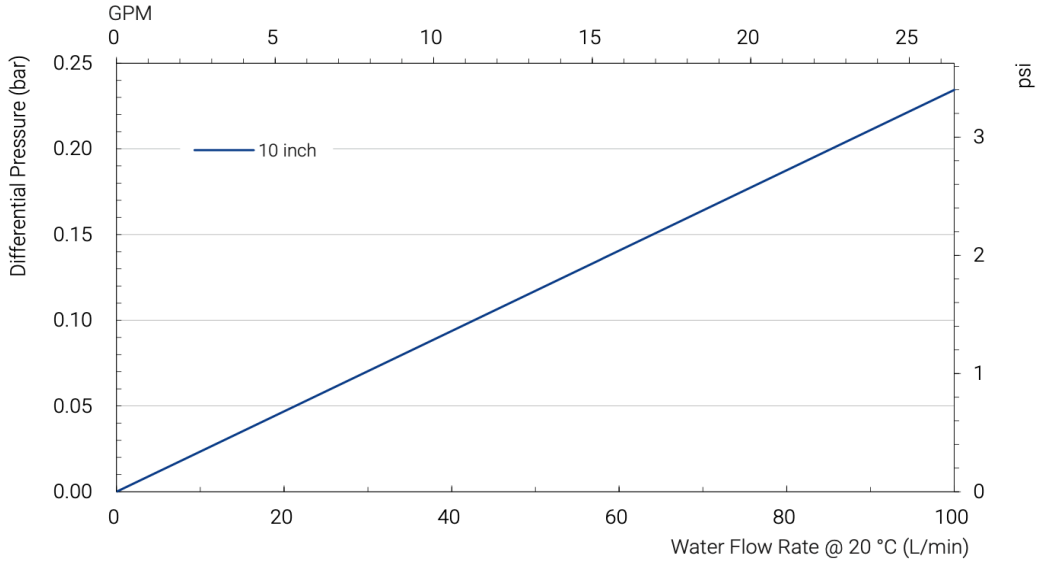
Water Flow Rate — Ultrafilter PF-PP 0.65 µm Cartridge Filter



Water Flow Rate — Ultrafilter PF-PP 0.8 µm Cartridge Filter



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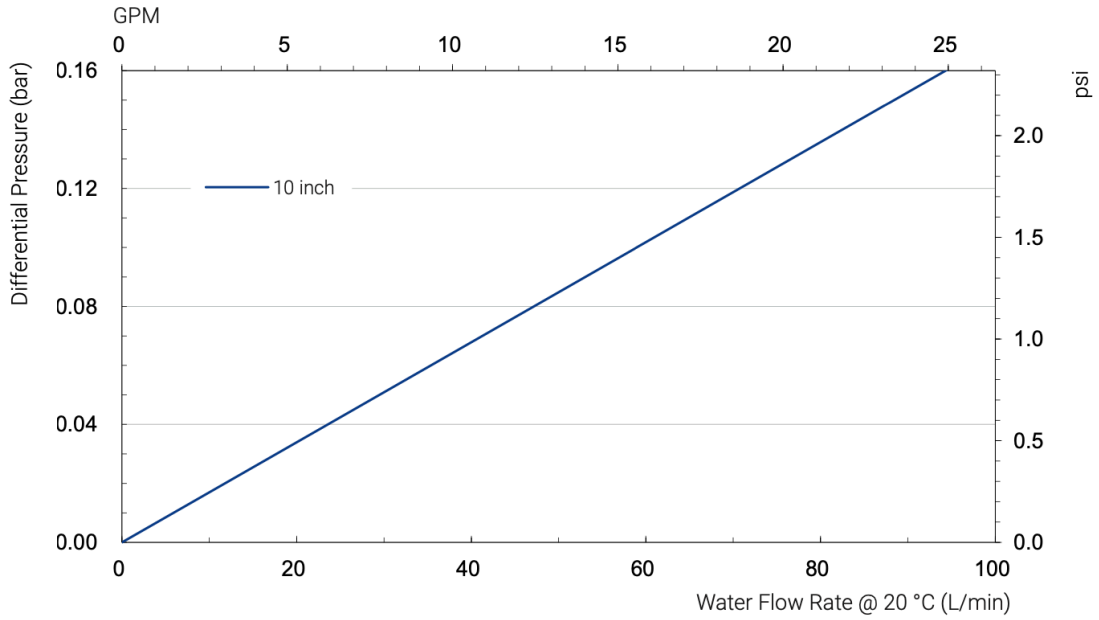
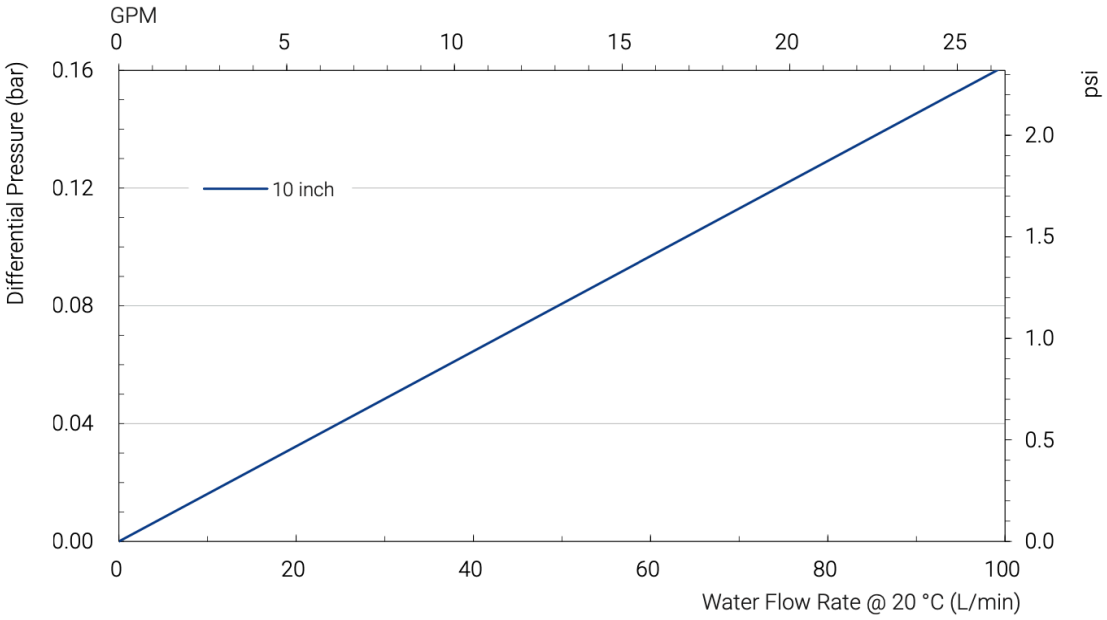
PF-PP

Water Flow Rate — Ultrafilter PF-PP 1.0 µm Cartridge Filter



Water Flow Rate — Ultrafilter PF-PP 3.0 µm Cartridge Filter



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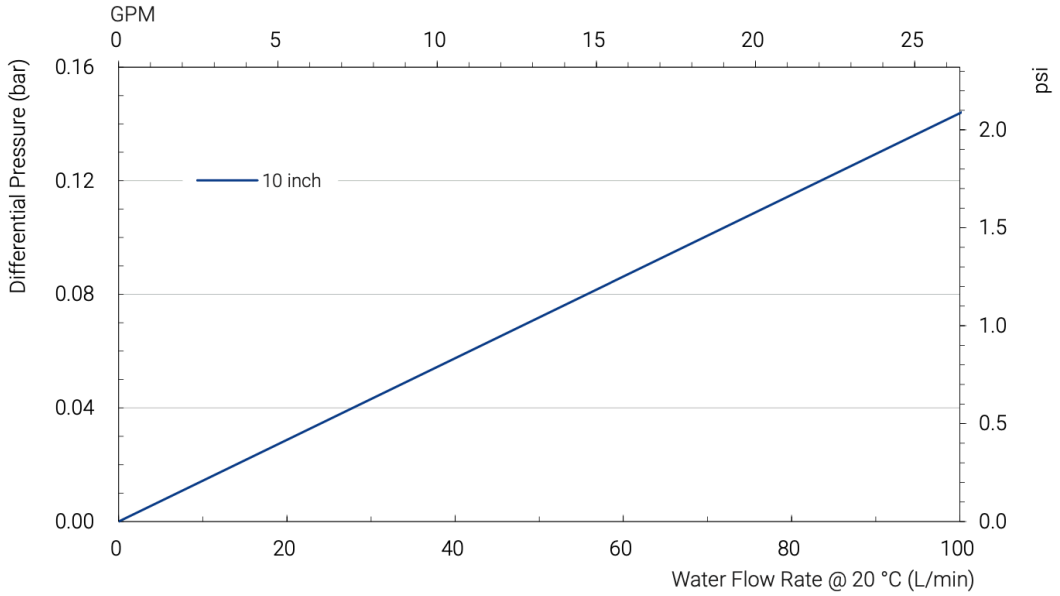
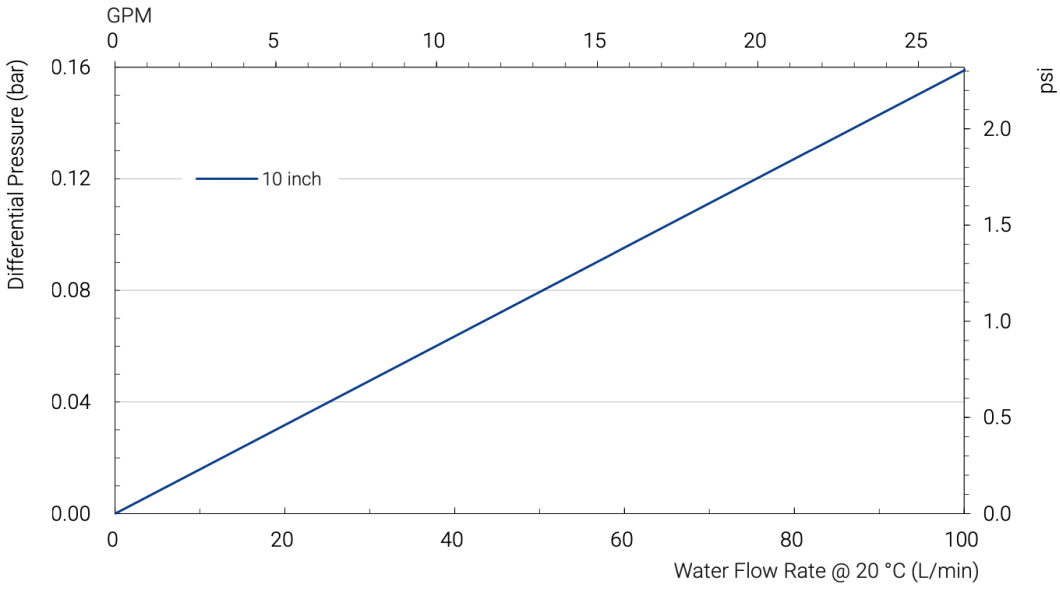
Water Flow Rate — Ultrafilter PF-PP 5.0 µm Cartridge Filter



Water Flow Rate — Ultrafilter PF-PP 6.0 µm Cartridge Filter



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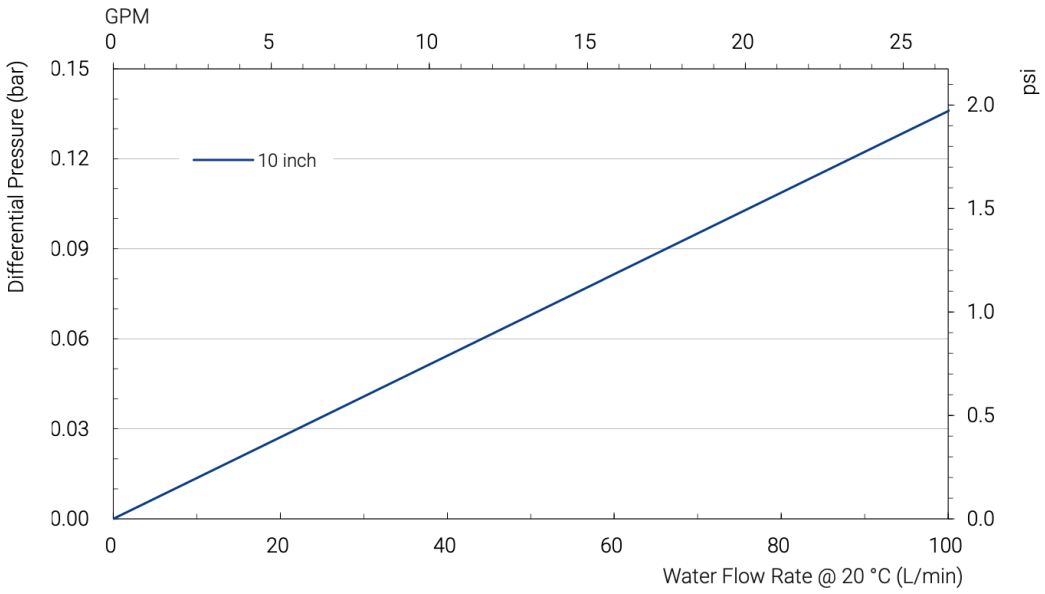
PF-PP

Water Flow Rate — Ultrafilter PF-PP 10.0 µm Cartridge Filter



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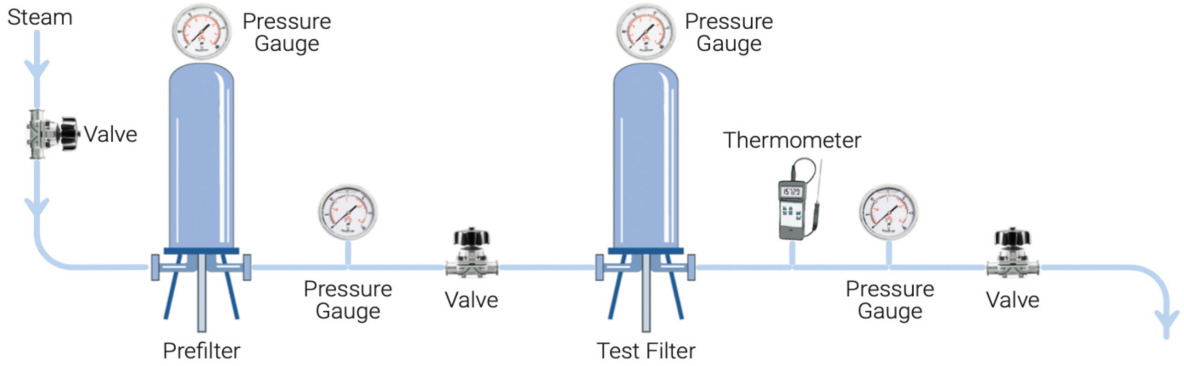
STERILIZATION AND SANITIZATION

1. Thermal Resistance

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

Ultrafilter PF-PP 0.2 µm cartridge filters were integrity tested prior to testing. The filters were steam sterilized at 125 °C for 30 minutes in the forward direction with 20 cycles under a differential pressure of less than 0.3 bar. The filters were validated by integrity test to analyze and evaluate the influences of multiple sterilization.

Schematic of Steam-in-Place



Ultrafilter PF-PP 0.2 µm cartridge filter

	FILTER INTEGRITY	
LOT NUMBER	PRIOR TO STERILIZATION	AFTER 20 SIP CYCLES
B140679627	Integral	Integral
B140699627	Integral	Integral
B140719627	Integral	Integral

Conclusion

The results indicate that the integrity of the Ultrafilter PF-PP 0.2 µm cartridge filter is not affected by the recommended sterilization methods.

ULTRAFILTER
THE FILTRATION MANUFACTURER
Kronsbein ultrafilter ®

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2. Hot Water Sanitization

Ultrafilter PF-PP 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-PP series cartridge filters were examined. As a result, recommendations and limits for multiple sanitization are given below.

Ultrafilter PF-PP 0.2 µm cartridge filters were 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.

Ultrafilter PF-PP 0.2 µm cartridge filter

	FILTER INTEGRITY	
LOT NUMBER	PRIOR TO SANITIZATION	AFTER 50 HOT WATER SANITIZATION CYCLES
B140679627	Integral	Integral
B140699627	Integral	Integral
B140719627	Integral	Integral

Conclusion

The results indicate that the integrity test of the Ultrafilter PF-PP 0.2 µm cartridge filter is not affected by the recommended sanitization methods.

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3. Chemistry Sanitization

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

Ultrafilter PF-PP 0.2 µm cartridge filters were integrity tested prior to testing. The cartridge filters were sanitized for 30 minutes at 40 °C with 50 cycles in the mixed 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.

Ultrafilter PF-PP 0.2 µm cartridge filter

	FILTER INTEGRITY	
LOT NUMBER	PRIOR TO SANITIZATION	AFTER 50 CHEMISTRY SANITIZATION CYCLES
B140679627	Integral	Integral
B140699627	Integral	Integral
B140719627	Integral	Integral

Conclusion

The results indicate that the integrity test of the Ultrafilter PF-PP 0.2 µm cartridge filter is not affected by the recommended sanitization methods.

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FDA 21 CFR INDIRECT FOOD ADDITIVE

The raw materials used in manufacture Ultrafilter PF-PP 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	Polypropylene	177.1520
Supports	Polypropylene	177.1520
Core, cage, end caps	Polypropylene	177.1520
O-rings	Silicone	177.2600
O-rings	EPDM	177.2600

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