Donaldson
FILTRATION SOLUTIONS

PROCESS FILTRATION
From Pure to Sterile

PES Capsule Filters

VALIDATION GUIDE
PES Capsule Filters

Contents

Thank You

Thank you for purchasing a quality-built Donaldson Filtration Solutions filter element. Donaldson takes pride in manufacturing state-of-the-art filtration for a variety of applications. Our commitment is to form lasting relationships with our customers by providing world-class products and service. If any questions or issues arise, do not hesitate to contact Donaldson.

Introduction

Donaldson Polyethersulfone (PES) Capsule filters are constructed in ISO-accredited clean rooms. Product quality and consistency are managed by ISO 9001 accredited quality control and manufacturing procedures, which are in place throughout all stages of manufacture.

Donaldson PES Capsule filters are 100% integrity tested during manufacture; ensuring filter integrity is not compromised. Data is reviewed and approved based on compliance to predetermined test specifications.

Statement

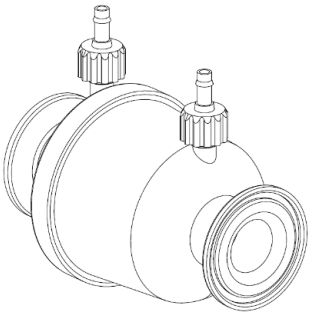
This Donaldson Filtration Solutions Product Validation Guide is for information only and without commitment and makes no claim to completeness in terms of configuration, features of coverage of every eventuality. This document does not represent any customized solution; it is intended solely to be of help with typical generic filter applications. You – as the user – are yourself responsible for the proper utilization of the described products. This document does not relieve you of the obligation to diligently select the conditions, nor of the obligation to exercise care in the use, installation, operation and maintenance of such products. By using this Product Validation Guide you recognize that Donaldson cannot be made liable for any damage beyond the scope of the provision described. We reserve the right to make changes to this document at any time without advance notice. The reproduction or transmission of this Donaldson document, either in whole or in part, is not permitted without the express written authority of Donaldson.

1. Product Description

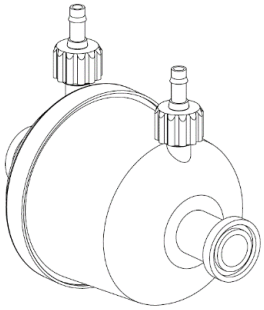
Materials of Construction

Membrane:	Polyethersulfone
Support Layers:	Polyester
Molded Components:	Polypropylene
Vent O-rings:	Silicone

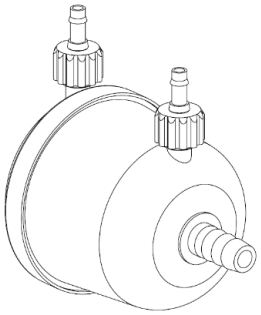
Connection Types



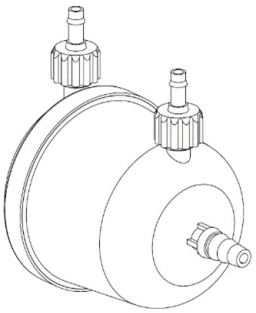
1 ½" Tri-Clamp



¾" Tri-Clamp



½" Stepped Hose Barb



¼" Stepped Hose Barb

Product Coding

		Actual Length	Connection	Part Number
2 Inch PES Capsule Filter	0.1 µm	124 mm (4.86 in)	1½" Tri-Clamp	AG1339501
		122 mm (4.80 in)	3/4 " Tri-Clamp	AG1339801
		130 mm (5.12 in)	1/2" Stepped Hose Barb	AG1340101
		128 mm (5.02 in)	1/4" Stepped Hose Barb	AG1340401
	0.2 µm	124 mm (4.86 in)	1½" Tri-Clamp	AG1339601
		122 mm (4.80 in)	3/4 " Tri-Clamp	AG1339901
		130 mm (5.12 in)	1/2" Stepped Hose Barb	AG1340201
		128 mm (5.02 in)	1/4" Stepped Hose Barb	AG1340501
	0.45 µm	124 mm (4.86 in)	1½" Tri-Clamp	AG1339701
		122 mm (4.80 in)	3/4 " Tri-Clamp	AG1340001
		130 mm (5.12 in)	1/2" Stepped Hose Barb	AG1340301
		128 mm (5.02 in)	1/4" Stepped Hose Barb	AG1340601
5 Inch PES Capsule Filter	0.1 µm	159 mm (6.24 in)	1½" Tri-Clamp	AG1340701
		157 mm (6.18 in)	3/4 " Tri-Clamp	AG1341001
		163 mm (6.40 in)	1/2" Stepped Hose Barb	AG1341301
		160 mm (6.30 in)	1/4" Stepped Hose Barb	AG1341601
	0.2 µm	159 mm (6.24 in)	1½" Tri-Clamp	AG1340801
		157 mm (6.18 in)	3/4 " Tri-Clamp	AG1341101
		163 mm (6.40 in)	1/2" Stepped Hose Barb	AG1341401
		160 mm (6.30 in)	1/4" Stepped Hose Barb	AG1341701
	0.45 µm	159 mm (6.24 in)	1½" Tri-Clamp	AG1340901
		157 mm (6.18 in)	3/4 " Tri-Clamp	AG1341201
		163 mm (6.40 in)	1/2" Stepped Hose Barb	AG1341501
		160 mm (6.30 in)	1/4" Stepped Hose Barb	AG1341801

2. Performance Test Data

Bacterial Retention

Introduction

The correlation between a non-destructive integrity test and the bacterial retention of a membrane filter is essential for filter elements used in sterile applications. The ASTM F838 "Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized For Liquid Filtration" describes the standard test procedure for the evaluation of filter elements for sterilizing liquids. Acholeplasma laidlawii (ATCC 23206), Brevundimonas diminuta (ATCC 19146), and Serratia Marcescens (ATCC 14756) are used as challenge organisms for the 0.1 µm, 0.2 µm and 0.45 µm products, respectively. The filters are challenged with a minimum of 10^7 organisms per square centimeter of effective filtration area per the defined method.

Results

Representative PES capsules for each media grade (0.1 µm, 0.2 µm, and 0.45 µm) were used for bacterial retention testing. The correlation between bubble point and bacterial challenge test results according to ASTM F838 are shown in the tables below.

0.1 µm (Acholeplasma laidlawii)			
Part ID	**Bubble Point (mbar, 50% IPA/ 50% water)**	**Titer Reduction (org/cm²)**	**Number of Organisms in Filtrate**
12524-006	2210	$>10^7$	<1 (Sterile)
12624-002	2070	$>10^7$	<1 (Sterile)
12724-012	2620	$>10^7$	<1 (Sterile)

0.2 µm (Brevundimonas diminuta)			
Part ID	**Bubble Point (mbar)**	**Titer Reduction (org/cm²)**	**Number of Organisms in Filtrate**
00124-011	3450	$>10^7$	<1 (Sterile)
00324-001	3450	$>10^7$	<1 (Sterile)
04223-07	3860	$>10^7$	<1 (Sterile)
04326-26	3860	$>10^7$	<1 (Sterile)
04423-26	3930	$>10^7$	<1 (Sterile)

0.45 µm (Serratia marcescens)			
Part ID	**Bubble Point (mbar)**	**Titer Reduction (org/cm²)**	**Number of Organisms in Filtrate**
11724-003	2070	$>10^7$	<1 (Sterile)
13024-001	2070	$>10^7$	<1 (Sterile)
12224-011	2890	$>10^7$	<1 (Sterile)
12324-002	2760	$>10^7$	<1 (Sterile)
12424-011	2620	$>10^7$	<1 (Sterile)

Conclusion

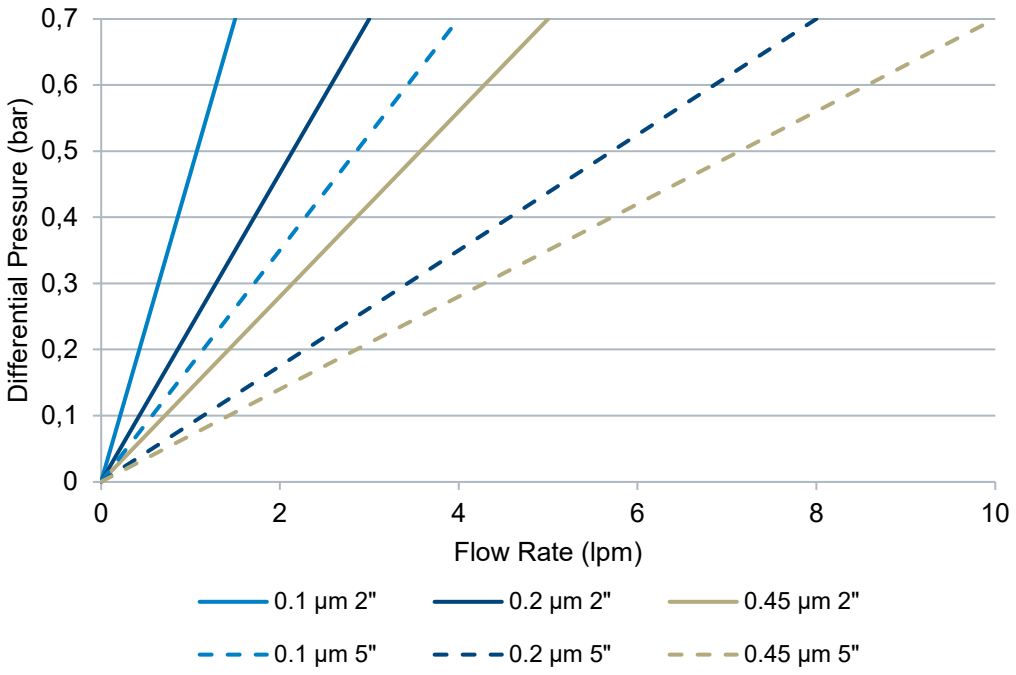
The table below summarizes the bubble point limits for each PES membrane grade to achieve a log-reduction value greater than seven for the correlated microorganism. The bubble point applies to both 2" and 5" capsule filters.

Table 1: Summary of bubble point correlation for each membrane grade and respective microorganism. Wetting fluid is included as it varies for the 0.1µm membrane grade.

Membrane Pore Size (µm)	Wetting Fluid	Minimum Bubble Point (mbar)	Microorganism
0.1	50% IPA/50% Water	2070	Acholeplasma laidlawii
0.2	Water	3450	Brevundimonas diminuta
0.45	Water	2070	Serratia marcescens

Flow Characteristics

Representative capsules for each PES membrane grade and length were tested to evaluate the flow characteristics. For all tests, a constant pressure of 0.7 bar was applied using 27°C water as the test fluid. The figure below shows the minimum flow rate per unit of applied pressure for each capsule style.



3. Resilience Test Data

Autoclaving

Representative PES capsules were autoclaved with at least 121°C steam for 40 cycles at a cycle duration of 30 minutes. The capsules were tested for bubble point using water as the wetting fluid before testing and after every 10 autoclave cycles.

Table 2: Autoclave sterilization data for PES capsules. The minimum allowable bubble point is 3450 mbar.

Part ID	0 Cycles	10 Cycles	20 Cycles	30 Cycles	40 Cycles
	Bubble Point (mbar)	Bubble Point (mbar)	Bubble Point (mbar)	Bubble Point (mbar)	Bubble Point (mbar)
0824-024	3500	4200	3600	4000	4000
0824-037	3800	4600	4000	3800	4000
0824-004	3800	3700	4000	3500	4000
0824-021	4500	3600	4000	3500	3800
0824-031	4300	4000	4000	3700	4000
0824-020	4100	4700	4500	3500	4000
0824-008	3600	4300	3600	3900	3500
0824-022	3700	4600	4000	4000	3600
0824-012	3800	3600	4000	4000	4000
0824-036	3900	3500	4000	3700	4000
0824-035	4200	4500	3700	4000	3700
0824-010	3500	4000	4000	3500	4000
0824-017	3700	4400	4000	4000	4000
0824-003	3700	4000	4500	4500	4200

All representative capsules lasted a minimum of 40 autoclave cycles. Incorporating a safety factor, PES capsules can withstand 30 autoclave cycles at 121°C with a cycle duration of 30 minutes.

Maximum Operating Conditions

Representative capsule filters were validated for maximum operating and differential pressure at 25°C and 80°C. Tests were conducted using 0.2µm filtered water operating in forward flow conditions. After each test, each filter was bubble point tested and challenged with bacteria to confirm integrity.

Table 3: Data for max operating condition testing at 25°C and 80°C. Each was conducted in the forward flow direction with 0.2µm water. The minimum allowable bubble point is 3450 mbar.

Part ID	Temperature (°C)	Upstream Pressure (bar)	Bubble Point (mbar)	Bacterial Retention Results
04223-42	25	5.0	4100	Sterile (<1 CFU)
04323-44	25	5.0	4100	Sterile (<1 CFU)
04423-43	25	5.0	4400	Sterile (<1 CFU)
04223-45	80	3.0	4000	Sterile (<1 CFU)
04323-47	80	3.0	4000	Sterile (<1 CFU)
04423-48	80	3.0	4000	Sterile (<1 CFU)

All tested capsules maintained integrity after challenged with both operating conditions. Incorporating a safety factor, capsules will remain integral at a maximum operating pressure of 4.0 bar at 25°C and at a maximum operating pressure of 2.0 bar at 80°C. Since the capsules act as both the filter housing and element, the maximum differential pressure of the capsule is equivalent to the maximum operating pressures as listed previously. The capsules have been validated to a maximum operating temperature of 80°C.

Maximum Reverse Pressure

Representative PES capsules were validated for maximum differential pressure when operating in reverse flow. Tests were conducted using 0.2 µm filtered water operating in reverse flow conditions at a pressure of 1 bar and a temperature of 25°C. After each test, each filter was bubble point tested and challenged with bacteria to confirm integrity.

Table 4: Data for reverse flow testing with representative PES capsules. Test conditions were 25°C and 1.0 bar with 0.2µm filtered water. The minimum allowable bubble point is 3450 mbar.

Part ID	Bubble Point (mbar)	Bacterial Retention Results
04223-37	4100	Sterile (<1 CFU)
04223-38	4300	Sterile (<1 CFU)
04223-39	4100	Sterile (<1 CFU)
04323-39	4000	Sterile (<1 CFU)
04323-40	4100	Sterile (<1 CFU)
04323-41	4300	Sterile (<1 CFU)
04423-44	4100	Sterile (<1 CFU)
04423-45	4000	Sterile (<1 CFU)
04423-40	4300	Sterile (<1 CFU)

All tested capsules maintained integrity after specified reverse flow conditions. Incorporating a safety factor, PES capsules can withstand a reverse differential pressure of 0.7 bar at 25°C.

4. Tests for Biological Safety

Biological Tests for Plastics (USP <88>)

PES capsules comply with Biological Reactivity Tests (Systemic Injection Test, Intracutaneous Test, and Implantation Test) as per USP <88> Class VI for Plastics.

Fiber Release (USP <788>)

Representative PES capsules were tested per USP <788> to confirm the filters meet the requirements for particulate release. Before each testing batch, the water used for testing was verified as particle-free per USP <788>.

Part ID	10 µm Particle Count per mL	25 µm Particle Count per mL
12524-003	14.47	2.07
12624-010	6.27	0.53
12724-004	5.73	0.53
12224-017	6.60	0.40
12324-017	6.93	0.47
12424-008	7.93	0.93
04223-33	3.53	0.20
04223-33	5.00	0.00
04223-33	7.00	0.20

All tested PES capsules have <25 particles per mL greater than 10µm and <3 particles per mL greater than 25 µm. Thus, the representative samples meet the requirements per USP <788>.

Bioburden Testing (ISO 11737)

Representative capsule filters were tested per ISO 11737 to quantify the amount of viable microorganisms on a product. Samples are incubated to evaluate the amount of colony-forming units (CFU) on a tested product.

Part ID	SCDA Count	RCA Count	SDA Count	Bioburden with Correction Factor (CFU)
03324-001	3	2	1	7.87
03324-002	15	7	2	31.47
03324-003	3	4	1	10.49
03424-004	2	1	1	5.24
03424-005	6	4	7	22.29
03424-006	2	3	9	18.36

PES capsules meet the bioburden limit defined per ISO11737 as each capsule tested had <1000 CFU.

Pyrogen / Endotoxin Test (USP <85>)

Representative capsule filters were tested per USP <85> to evaluate the concentration of endotoxin units (EU) per unit volume of sample extract.

Part ID	Blank Concentration (EU/ml)	Test Sample Concentration (EU/ml)
12524	≤0.03	≤0.03
12624	≤0.03	≤0.03
12724	≤0.03	≤0.03
12224-003	≤0.03	≤0.03
12324-011	≤0.03	≤0.03
12424-003	≤0.03	≤0.03
04223-33	<0.06	<0.12
04223-33	<0.06	<0.12
04223-33	<0.06	<0.12

The maximum observed endotoxin concentration for PES capsules was <0.12 EU/ml

5. Food Contact Compliance

US FDA

As per the table below, all manufacturing components are FDA-listed for food contact use in accordance with the Code of Federal Regulations (CFR) Title 21.

Component	Materials of Construction	FDA Compliance
Membrane	Polyethersulfone	CFR 177.2440
Support Layers	Polyester	CFR 177.1630
Molded Components	Polypropylene	CFR 177.1520
Vent O-rings	Silicone	CFR 177.2600

EU

All manufacturing components comply with the requirements of European Regulation (EU) No 10/2011, wherever the material is subject to this guideline, as well as in Regulation (EC) No 1935/2004.

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Contact us

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