

LeSiever® Mycoplasma Retention Capsule Filters with 0.1µm PES LeSiever® Mycoplasma Retention Capsule Filters with 0.2/0.1µm PES

Due to small size and lack of a rigid cell wall, mycoplasmas are particularly good at penetrating traditional 0.2 µm rated sterilizing grade filters. 0.1 µm rated filters can be used for protection from mycoplasma contamination. LeSiever® mycoplasma retention capsule filters contain an asymmetric 0.1 µm or 0.2/0.1 µm hydrophilic membrane that offers the greatest assurance of mycoplasma retention. Mycoplasma removal filtration is very important in cell culture, because mycoplasma contaminate mammalian cell lines and cell culture media, as a result in reduced cell activity and product yield.

LeSiever® Mycoplasma retention Filters are used in wide applications, including filtration of cell and tissue culture media, microbiological growth media, additives, active ingredients.



Typical applications

LeSiever® Mycoplasma Retention Capsule Filters offer high quality filtration in a wide variety of applications.

- ⦿ Cell and tissue culture media
- ⦿ bacterial culture broth
- ⦿ Media additives
- ⦿ Serum
- ⦿ Protein solutions
- ⦿ process intermediates
- ⦿ Concentrated protein

Specification

LeSiever® Mycoplasma Retention Capsule Filters are available in double layer 0.2/0.1 µm and single layer 0.1 µm PES membrane, and multiple configurations that vary by filtration area and type of inlet/outlet connection.

⦿ LeSiever® Mycoplasma Retention Capsule Filters with 0.2/0.1µm PES

For double layer filters, have an 0.2 µm PES prefilter, which protects the sterilizing-grade and mycoplasma removal 0.1 µm PES membrane from early plugging and increases filtration capacity. Both 0.2 and 0.1 µm PES membrane layer ensures sterility of the filtrate but the final 0.1 µm membrane layer will remove mycoplasma. Heterogeneous double layer sterilizing PES membrane can be used for plasma proteins, serum, vaccines and process intermediates.

⦿ LeSiever® Mycoplasma Retention Capsule Filters with 0.1µm PES

0.1 µm single layer sterilizing PES membrane is for particle-free liquids such as buffer, cell and tissue culture media, media additives, pharmaceutical water.

Advantage

- ⦿ Permanently hydrophilic PES membrane
- ⦿ Low proteins binding and high transmission of active ingredients
- ⦿ Broad chemical compatibility through pH range 1–14
- ⦿ High flow rates at low pressure drops
- ⦿ Provide 0.2/0.1 µm double layer format and 0.1 µm single layer format
- ⦿ Sterilizing-grade filtration and mycoplasma removal
- ⦿ 100% integrity tested during manufacture
- ⦿ Available with a variety of connectors

Technical specification

Size	Size 1	Size 5	2"	4"	5"	10"
Filtration Area m ² ft ²	0.018 0.19	0.055 0.59	0.13 1.4	0.23 2.5	0.33 3.6	0.66 7.1
Pore size (µm)	0.1, 0.2/0.1					
Materials of Construction						
Filter media	Polyethersulfone (PES), hydrophobic					
Structural components	Polypropylene					
O-ring	Silicone (SI)					
Supports	Polypropylene					
Maximum Pressure						
Forward mbar (psi) at 23°C	4000 (58)	5000 (73)	5000 (73)	5000 (73)	5000 (73)	5000 (73)
Reverse mbar (psi) at 23°C	2000 (29)	2500 (36)	2500 (36)	2500 (36)	2500 (36)	2500 (36)
Integrity Test						
Diffusion Test @ 2800 mbar 41 psi, mL/min	≤1.6	≤3.6	≤4.8	≤7.2	≤10	≤15
Bubble Point, at 23 °C, mbar (psi)	≥2400 (35)					
Bacterial Retention	Quantitative retention of 107 CFU/cm2 <i>Brevundimonas diminuta</i> (ATCC® 19146) per ASTM® F838-83 methodology					
Mycoplasma Removal	Typical Log Reduction Value (LRV) >7 A. laidlawii ATCC® 23206					
Toxicity	Meet the requirements of USP 88					
TOC/Conductivity	Effluent meets the WFI criteria for USP <643>, Total Organic Carbon, and USP <645>, Conductivity, after a WFI water flush of: 5.5 L at 25 °C and 10 L at 25 °C					
Oxidizable Substances	Effluent meets the requirements for USP Sterile Water for Injection after a water flush of: 1000 mL.					
Bacterial Endotoxins	Aqueous extraction contains ≤0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test					
Gravimetric Extractables	≤1.0 mg in 70/30 % IPA/water					
Sterilization						
gamma compatible format	Gamma irradiation 25-40 kGy					
autoclavable format	5 autoclave cycles of 60 min @ 126 °C					
Non-Fiber Releasing	Component materials meet the "non-fiber releasing" criteria as defined in 21 CFR 210.3 (b) (6).					
Component Material Toxicity	Component materials meet the criteria of the USP <87>, USP <88>					

Ordering information

LeSiever® Mycoplasma Retention Capsule Filters

P	1	S	2	D	0 5	T T	1
Product Code	Product type	Membrane Material	Pore Size	Sterilization	Size	Inlet/Outlet	Packaging
P: Pharmaceutical Grade	1: Capsule filter	S: Hydrophilic PES	2: 0.1 µm 6: 0.2/0.1 µm	D: Gamma compatible A: Autoclavable S: sterile (gamma irradiated)	S1: 180cm ² S5: 550cm ² 02: 2inch 04: 4inch 05: 5inch 10: 10inch	T: 3/2" (38.1mm) Tri-Clamp F: 3/4" (19.1mm) Tri-Clamp H: 1/2" (12.7mm) Hose Barb O: 1/4" (6.4mm) Hose Barb	1: 1/pack 3: 3/pack 4: 4/pack 6: 6/pack M=Manufacture

Size	Number(Single layer 0.1 μm)	Number(double layer 0.2/0.1 μm)	Filtration Area	Package
S1	P1S2DS1--6	P1S6DS1--6	180cm ²	6/pack
S1	P1S2AS1--6	P1S6AS1--6	180cm ²	6/pack
S1	P1S2SS1--6	P1S6SS1--6	180cm ²	6/pack
S5	P1S2DS5--4	P1S65DS5--4	550cm ²	4/pack
S5	P1S2AS5--4	P1S6AS5--4	550cm ²	4/pack
S5	P1S2SS5--4	P1S6SS5--4	550cm ²	4/pack
2inch	P1S2D02--4	P1S6D02--4	0.13m ²	4/pack
2inch	P1S2A02--4	P1S6A02--4	0.13m ²	4/pack
2inch	P1S2S02--4	P1S6S02--4	0.13m ²	4/pack
4inch	P1S2D04--3	P1S6D04--3	0.23m ²	3/pack
4inch	P1S2A04--3	P1S6A04--3	0.23m ²	3/pack
4inch	P1S2S04--3	P1S6S04--3	0.23m ²	3/pack
5inch	P1S2D05--1	P1S6D05--1	0.33m ²	1/pack
5inch	P1S2A05--1	P1S6A05--1	0.33m ²	1/pack
5inch	P1S2S05--1	P1S6S05--1	0.33m ²	1/pack
10inch	P1S2D10--1	P1S6D10--1	0.66m ²	1/pack
10inch	P1S2P10--1	P1S6P10--1	0.66m ²	1/pack
10inch	P1S2S10--1	P1S6S50--1	0.66m ²	1/pack

--Inlet/Outlet:

H = 12.7 mm 1/2" Hose Barb

F = 19.1 mm 3/4" Tri-Clamp (Size 1 Only)

O = 6.4 mm 1/4" Hose Barb (Size 1 Only)

*Packaging:

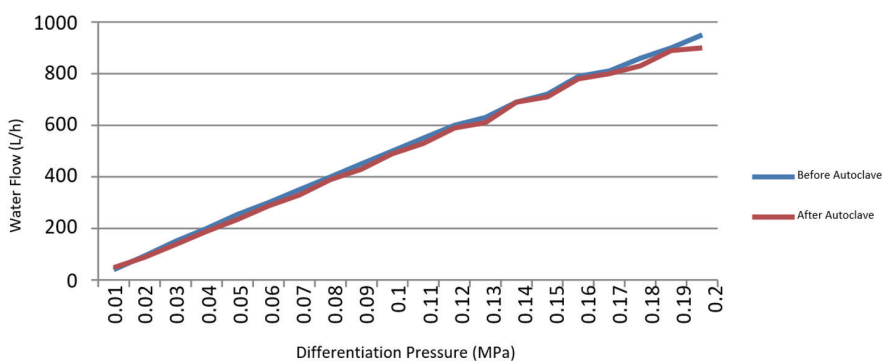
1 = 1/pack (5", 10")

3 = 3/pack (4")

4 = 4/pack (2")

6 = 6/pack (Size 1)

Standard Flow Rate versus Pressure Drop



S5