

CLARIFLOW®-P

STERILIZING GRADE FILTER

Clariflow-P pharmaceutical filter cartridges have been developed and optimized to assure end-product sterility in the filtration of solutions used in biopharmaceutical and pharmaceutical applications. Clariflow-P use double layer of a mirrored-anisotropic polyethersulfone (PES) membrane on its 0.2µm version to guarantee a consistent removal of microorganisms and full sterilizing grade retention.

Clariflow-P is manufactured with polypropylene components and an inherently hydrophilic PES membrane that contains no added surfactants or wetting agents. The PES membrane also exhibits low protein-binding characteristics, is biologically inert, and is full bacterial retentive (LRV >7).

Each cartridge is fabricated in a cleanroom environment, pre-flushed with deionized water, and 100% integrity tested prior to shipment.

FEATURES & BENEFITS

- Bacterial retention validated in accordance with current version of ASTM F838 liquid bacterial challenge using *Brevundimonas diminuta*:
 - Sterilizing grade filtration
- Double layer of Sterilizing 0.2µm PES membrane:
 - Redundant bacterial retention within same filtration device.
- Integrity testing parameters correlated to bacterial retention:
 - For non-destructive integrity test to confirm sterilizing filtration
- Biologically inert and a low protein binding nature due to its construction materials:
 - Maximizes chemical compatibility and product yields
- PFAS free construction:
 - Polypropylene components and PES filtration media
- Extractables and Leachables tested: All product presentation tested per current USP <665> guidelines for moderate-risk

APPLICATIONS

Sterilizing grade filtration of:

- Pharmaceutical Products
- Parenteral Solutions
- Ophthalmic Solutions
- Diagnostic Reagents
- Biological Growth Media
- Concentrated Proteins
- Vaccines
- Downstream Purification Bioproducts
- Chromatography Column Buffers
- Blood and Plasma Fractionation
- Water for Injection



TECHNICAL SPECIFICATIONS

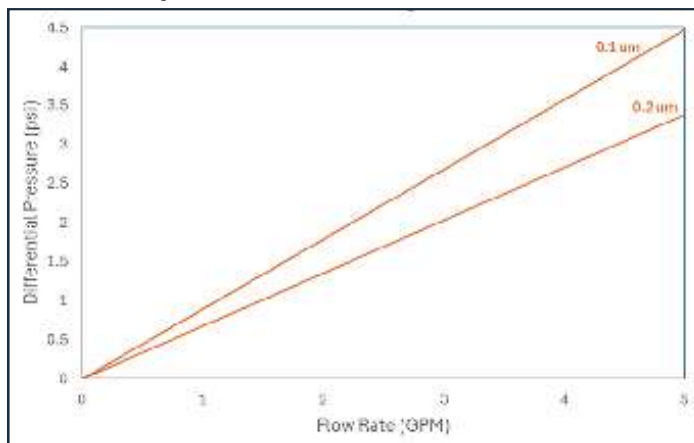
Cartridge and Mini Cartridge:	
Filtration Membrane	Polyethersulphone
Upstream Support	Polypropylene
Downstream Support	Polypropylene
Inner Core	Polypropylene
Outer Cage	Polypropylene
End Caps	Polypropylene
Endcap Inserts	Polypropylene encapsulated 316L Stainless Steel, grafted Polysulphone
O-rings	Silicone, EPDM, Buna-N, Viton
Mini Capsules	
Body	Polypropylene
Connections	Polypropylene
Vent O-rings	Silicone, EPDM, Buna-N, Viton

EFFECTIVE FILTRATION AREA (EFA)

Size	Area (ft²)	Area (m²)
10 inch Cartridge	6.2	0.58
5 inch Cartridge	3.1	0.29
Mini Cartridge	2.1	0.20
Double Size Mini Capsule	2.1	0.20
Standard Size Mini Capsule	1.6	0.15
Half Size Mini Capsule	0.8	0.07

WATER FLOW RATES

10 inch Cartridge

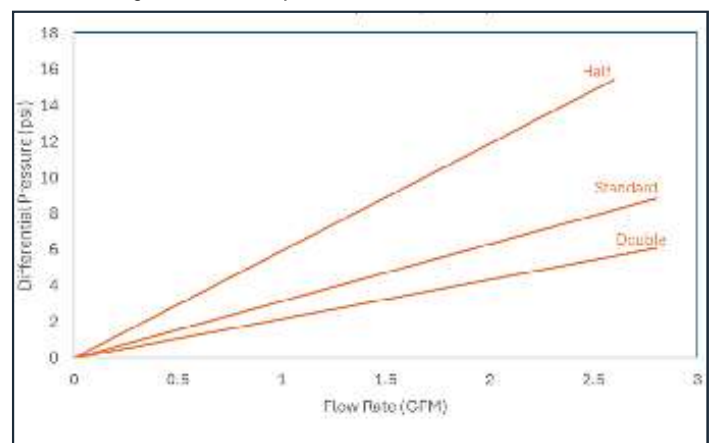


INTEGRITY TEST DATA

Rating	Bubble Point	Diffusional Flow	
µm	Min psi (bar)	Max value (ml/min)	Test Pressure psi (bar)
10" Cartridge			
0.1*	45 (3.1)	25	55 (3.8)
0.2	55 (3.8)	20	45 (3.1)
5" Cartridge			
0.1*	45 (3.1)	24	55 (3.8)
0.2	55 (3.8)	10	45 (3.1)
Mini Cartridge & Double Size Mini Capsule			
0.1*	45 (3.1)	17	55 (3.8)
0.2	55 (3.8)	8	45 (3.1)
Standard Size Mini Capsule			
0.1*	45 (3.1)	13	55 (3.8)
0.2	55 (3.8)	6	45 (3.1)
Half Size Mini Capsule			
0.1*	45 (3.1)	6	55 (3.8)
0.2	55 (3.8)	3	45 (3.1)

*Values based on wetted membrane with IPA: H2O (60%/40%) solution.

Mini Cartridge and Mini Capsules



Note: Water flow rate for a Mini Cartridge is the same as for a Double Size Mini Capsule, the above graph applies for both presentations.

MAXIMUM OPERATING CONDITIONS

Differential Pressure

Cartridge: 80 psid (5.5 bar) @ 75°F (24°C)

Mini Capsule: 80 psid (5.5 bar) @ 75° F (24°C)

Steam Sterilization and Autoclave

Cartridge: Maximum 30 cycles of 30 minutes @ 257°F (125°C)

Mini Capsule: Max 10 Autoclave cycles of 30 mins @ 268°F (131° C)

Bacterial Retention

Clariflow-P filters have been validated as a full sterilizing grade filters. They provide sterile filtrate when challenged with a liquid bacterial culture in accordance with current revision ASTM F838.

Biological Safety

All construction material in Clariflow-P conform with current biocompatibility testing per UPS <87>, <88> and <665> for moderate risk.

Product Assurance

Products are packaged and sealed in a protective polyethylene bag within a controlled manufacturing environment. Every filter device is integrity tested and flushed with DI water before shipment.

Packaging Options

- Non-sterile as a standard option
- Pre-sterilized mini capsule by autoclave

ORDERING INFORMATION

Cartridges:

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Insert Style	
Code	Description
5	Encapsulated 316L SS
6	Encapsulated Polysulfone

End Fitting	
Code	Description
2	226/Flat
3	222/Flat
7	226/Fin
8	222/Fin

Nominal Length	
Code	Length
05	5" (130 mm)
10	10" (250mm)
20	20" (500mm)
30	30" (750mm)
40	40" (1000mm)

Filter Rating	
Code	Micron
001	0.1
002	0.2

O-Ring	
Code	Material
0	Buna N
1	EPDM
2	Silicone
4	Viton®
N	None

Mini Cartridges:

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Filter Rating	
Code	Micron
002	0.2

O-Ring	
Code	Material
0	Buna N
1	EPDM
2	Silicone
4	Viton®
N	None

Mini Capsules:

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Size	
Code	Description
H	Half
S	Standard
D	Double

Inlet/Outlet	
Code	Length
B	1/4" Hose Barb
H	1/2" Hose Barb
S	1 1/2" Sanitary Flange
D	Walther 3/8 Male
P	1/4" NPT (Male)
J	1/2" NPT (Male)
K	5/8" NPT (Female)
G	1/2" Swagelok®

Filter Rating	
Code	Micron
002	0.2

Vent O-Ring	
Code	Material
0	Buna N
1	EPDM
2	Silicone
4	Viton®
N	None

Standard Package Options	
Blank	Non-Sterile
S	Pre-Sterilized

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