Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Data Sheet

Viresolve® Prefilter

Adsorptive prefilters for removing protein aggregates

Viresolve® Prefilters are designed to improve the robustness of virus filtration operations by efficiently removing protein aggregates. Implementing a prefilter minimizes variability in virus filter capacity caused by different batches of product, hold steps or freeze-thaw. Implementing the Viresolve® Prefilter results in more consistent filtration performance, improving the capacity of the Viresolve® Pro Device, and overall process economics.

Benefits

- Improve process robustness by minimizing feed variability
- Increase Viresolve® Pro Device capacity
- Does not impact product yield
- Predictable scale-up

Filter formats

- OptiScale® 40 disposable capsule filters for process development and optimization
- Pod filters (0.11 m^2, 0.55 m^2, 1.1 m^2) for easily scalable pilot to process applications

MilliporeSigma is the U.S. and Canada
Life Science business of Merck KGaA,
Darmstadt, Germany.

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Quality Management System

All Viresolve® Prefilters are designed, developed, and manufactured in accordance with a Quality Management System approved by an accredited registering body to ISO 9001 standards. Pods are integrity tested during manufacturing and supported by a validation guide. For traceability and easy identification, each filter is labeled with the product name and identifying characteristics. Every filter is supplied with a Certificate of Quality.

Viresolve® Prefilter Provides High Protein Yield

Table 1. Yield Analysis

Source	Recovered Mass
Filtrate	94.50%
Flush	2.20%
System hold-up loss	2.50%
Total	99.20%

Viresolve® Prefilter increases Viresolve® Pro Device capacity

Figure 1 shows the increased capacity of the Viresolve® Pro Device with the Viresolve® Prefilter device upstream. Testing was performed with a human IgG (4 g/L) feed stream under different pH and conductivity conditions.

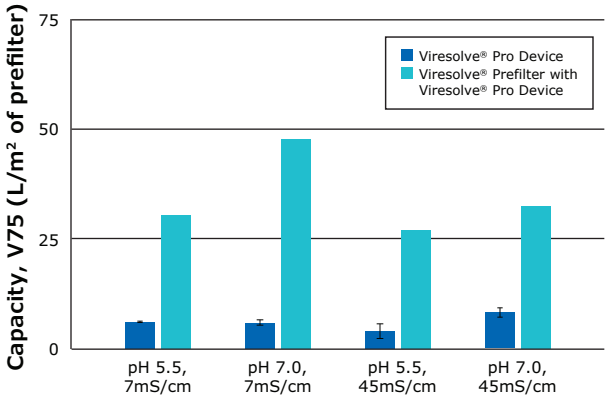

Figure 1. Viresolve® Prefilter improves Viresolve® Pro Device capacity under different pH and conductivity conditions.

Figure 2 shows the increased capacity of Viresolve® Pro Devices with the Viresolve® Prefilter and a panel of monoclonal antibodies. The Viresolve® Prefilter increased mean mass capacity of the Viresolve® Pro Device from 5 kg/m² to 13 kg/m².

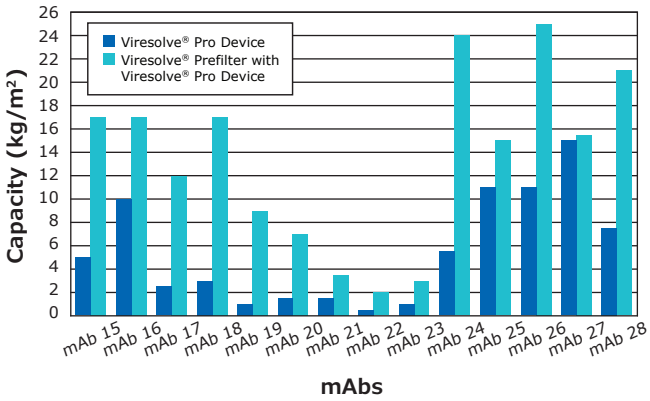

Figure 2. Viresolve® Prefilter improves the capacity of the Viresolve® Pro Device with multiple mAb feed streams.

Specifications

	OptiScale®-40	0.11 m^2 Pod	0.55 m^2 Pod	1.1 m^2 Pod
Effective Filtration Area	5.0 cm^2	0.11 m^2	0.55 m^2	1.1 m^2
Materials of Construction				
Media:	Cellulose fibers with inorganic filter aid	Cellulose fibers with inorganic filter aid		
Membrane:	Mixed esters of cellulose	Mixed esters of cellulose		
O-ring:	—	—		
Flat seal:	—	Thermoplastic elastomer		
Housing:	Polypropylene	Glass-filled polypropylene		
Standard Connections	Female Luer-Lok, male luer slip fittings	Disposable 1 1/2 in. TC fitting		
Vent/Drain	—	Disposable vent		
Maximum Operating Line Pressure (at 23 °C)	4.1 bar (60 psi)	3.4 bar (50 psi)		
Maximum Differential Pressure (at 23 °C)				
Forward:	2.1 bar (30 psi)	2.1 bar (30 psi)		
Reverse:	0.03 bar (0.5 psi)	2.1 bar (30 psi)		
Autoclaving	May be autoclaved for 3 cycles of 60 minutes at 123 °C.	May be autoclaved for 3 cycles of 60 minutes at 123 °C.		
TOC/Conductivity	—	Lot release testing on effluent exhibited TOC <4 ppm and conductivity <10 µS/cm after 3 autoclave cycles and a purified water flush of 100 L/m^2.		
Metals (24 hour static soak post autoclave and flush)	—	Pb < 0.01 mg/ft^2 Hg < 0.01 mg/ft^2 As < 0.012 mg/ft^2 Fe < 0.1 mg/ft^2 Al < 0.5 mg/ft^2		
Bacterial Endotoxin	Aqueous extraction contains <0.25 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test (filter media only) according to USP <85>, EP 2.6.14 and JP 4.01.			
Component Material	All wetted component materials were tested and meet the criteria for Biological Reactivity Testing.			
Indirect Food Additive	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182.			
Quality Standard	These products are manufactured in accordance with a Quality Management System that is approved by an accredited registering body to the ISO 9001 Quality Systems Standard.			

Ordering Information

Device	Nominal Process Volume	Connections	Qty/Pk	Cat. No.
OptiScale®-40 Capsule	100 mL	Female Luer-Lok, male luer slip fittings	9	**SSPV A40 NB9**
0.11 m^2 Pod Filter	20 – 40 L	Disposable 1 1/2 in. TC inlet and outlet	1	**MSPV 01 FS1**
0.55 m^2 Pod Filter	100 – 200 L	Disposable 1 1/2 in. TC inlet and outlet	1	**MSPV 05 FS1**
1.1 m^2 Pod Filter	200 – 400 L	Disposable 1 1/2 in. TC inlet and outlet	1	**MSPV 10 FS1**

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To place an order or receive technical assistance

For additional information, please visit **SigmaAldrich.com**
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