Data Sheet

Viresolve® NFP Filter

Fast, reliable parvovirus removal

Viresolve® NFP filters with Viresolve® NFP (Normal Flow Parvovirus) membranes clear parvovirus from recombinant or human plasma sources, without compromising flow rates. Viresolve® NFP filters add speed and dependability to viral clearance in therapeutic drug manufacturing applications. Operated in normal flow filtration mode, these filters are ideal for monoclonal antibody polishing applications eliminating small virus contaminants from essential media and feed streams containing dilute peptides. When placed upstream of bioreactors, Viresolve® NFP filters minimize infection risk caused by viruses common to mammalian cell expression systems.

For plugging streams we recommend the Viresolve® Prefilter for use with Viresolve® NFP filters. This robust filter configuration improves NFP filter capacity significantly reducing your overall virus filtration costs.

Rapid, Reliable

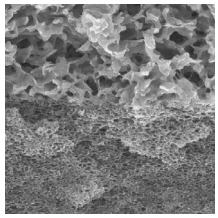
Composed of a PVDF material, Viresolve® NFP membranes possess a unique pore structure with characteristics that enhance filtration efficiency. Excellent flow-through qualities allow NFP membranes to provide highly efficient separations at flow rates 6 to 10 times faster than competitive products. Inherent size-exclusion properties reliably retain specific-sized contaminants, improving product safety and protecting downstream processes.

Membrane Type

- PVDF membrane

Filter Formats

- OptiScale®-25 disposable capsule filters
- Opticap® XL and XLT disposable capsule filters
- Cartridge filters



SEM of composite membrane structure.

Benefits

- >4 log removal of small viruses
- >98% recovery
- 6 – 10x faster than competitive filters
- 15-minute, alcohol-free integrity testing
- Simple, predictable scale-up
- Multiple formats available

The Viresolve® Prefilter is available for use in series with Viresolve® NFP filters. The prefilter effectively removes fouling material from biotech feeds and improves filtration economics by protecting the Viresolve® NFP viral clearance filters.

Convenient and Easy to Use

Autoclavable, easily installed, and quickly integrity tested, single-use Viresolve® NFP filters are designed to minimize the time and expense associated with assembling, cleaning and validation. Easy-turn valves for vent adjustments on our disposable capsules allow precise process control. O-ring seals, flow direction arrows, and the option for hose barb connections molded onto housings ensure a tight fit and proper orientation during installation.

Predictable Scaling, Linear Performance

Linear performance between sizes supports fast scale-up and scale-down for most biopharmaceutical processes.

Delivers High-Quality Filtered Protein

Unlike inactivation methods, filters are inert and do not degrade proteins. High protein passage and low protein binding provide >98% protein product yields. Low extractables ensure product quality.

Viresolve® NFP size-exclusion membrane technology passes proteins up to 160 kD in size and consistently clears parvovirus at >4 logs, without compromising flow rate.

Regulatory Compliance

All Viresolve® NFP filters are designed, developed, and manufactured in accordance with good manufacturing practices under an ISO® 9001 Quality Management System. Viresolve® NFP small area devices, capsules and cartridges are integrity tested during manufacturing and supported by a Validation Guide to assist in compliance with regulatory requirements. For traceability and easy identification, each filter is labeled with the product name and identifying characteristics. Every Viresolve® NFP filter is shipped with a Certificate of Quality.

Superior Performance

Performance of Viresolve® NFP filters complies with FDA, EMA, ICH, and PEI regulatory agencies for use as a dedicated virus reduction process step.

Virus Challenge Study Results

		LRV Post		
Porcine Challenge	Challenge Fluid	10 mL	25 mL	50 mL
30 psi	2.5 mg/mL MAb*	>4.7 – >5.6	>4.7 – >5.6	>4.7 – >5.6
45 psi	2.5 mg/mL MAb	>4.7 – >5.7	>4.7 – >5.7	>4.7 – >5.7
30 psi	DMEM*	>6.9 – >7.0	>6.9 – >7.0	>6.9 – >7.0
45 psi	DMEM	>6.2	>6.2	>6.2

*LRV reported from two separate tests performed with two virus titers.

Porcine parvovirus has been evaluated in Viresolve® NFP validation studies in the presence of protein. Dulbecco's Modified Essential Media (DMEM) containing a spike of porcine parvovirus provided clearance in excess of 6 logs.

Water Wettable

Hydrophilic membrane is water wettable and does not require the use of solvents such as alcohol for integrity testing. Integrity tests can be completed in just 15 minutes. Wetting with 12 L of water per 10 in. element will meet the current USP total organic carbon (<500 ppb) and conductivity (<1.3 mS/cm) regulations for water for injection at 25 °C.

Fast Integrity Test

A convenient air-water diffusion based integrity test has been developed. Passing this test provides assurance of consistent and reliable virus retention. Integrity tests can be completed in just 15 minutes.

The Right Size

Viresolve® NFP membranes are offered in multiple device configurations that vary by filtration area and inlet/outlet connection type. Viresolve® NFP filter units are available as 25 mm devices, capsules, and cartridges that accommodate volumes ranging from 70 mL through thousands of liters at process scale.

Sizing

Sizing requires bench scale trials with small volumes of representative fluid samples, 25 mm OptiScale®-25 capsules, the Low Hold Up Volume V_{max}™ Test Kit, and comparable operating parameters to production. Flow decay is measured to assess the capacity of the filter. The volume per surface area of the trial then translates to the area needed to process a specific batch size.

The Viresolve® Prefilter will improve the filtration economics of the viral clearance step by providing protection for Viresolve® NFP viral clearance filters. Use of this prefilter with NFP will improve capacity and increase the life of the NFP filter. Available in scalable filter formats, this prefilter will easily fit in existing development and manufacturing processes.

OptiScale®-25 Small Volume Disposable Capsule Filters

OptiScale®-25 Filters

OptiScale®-25 capsules with Viresolve® NFP membrane are used in small volume applications where feedstock requirements are minimal. Providing an active filtration area of 3.5 cm^2, these small devices are useful as an evaluation tool for impurity studies, protein passage studies, membrane area determination, and virus validation. A female Luer-Lok™ fitting/male Luer slip connection ensures fast and secure setup.

OptiScale®-25 disposable capsule filters are sold as Evaluation Kits. Each kit including 9 capsules, either 3 devices each of 3 different membrane lots or 9 devices from a single membrane lot. These are ideal for use in validation and sizing studies with the Low Hold Up Volume V_{max}™ Test Kit.

Cartridge Filters

Cartridge Filters

Viresolve® NFP 10-, 20- and 30-inch cartridge filters are ideally suited for processes that require maximum pressure differentials. Each cartridge is integrity tested during the manufacturing process. A range of filtration areas is available to suit medium and large volume requirements.

Viresolve® Prefilters – Available in 2 Formats

OptiScale®-40 Small Volume Disposable Capsule Filters provide an active filtration area of 5 cm^2. These devices are useful for process development, optimization, and viral clearance studies.

Pod Disposable Devices are scalable from pilot to process applications. This new innovative NFF device format offers process flexibility and linear scale-up. The platform consists of three Pod sizes, 0.11 m^2, 0.55 m^2 and 1.1 m^2, and an expandable holder system. The pilot scale holder is configurable with extension rods that can accommodate up to five 1.1 m^2 Pods, while the process scale holder expands to mount from 5 to 30 Pod devices. The stainless steel holder is not wetted by product and the connectors are disposable plastic.

Opticap® XL and XLT Disposable Capsule Filters

Opticap® XL Filters

Opticap® XLT Filters

XLT Capsule Stand

Convenient and Easy to Use

Opticap® XL and XLT capsule filters eliminate the time and expense associated with assembling, cleaning, and validating stainless steel housings. Adjustable, easy-to-turn, upstream vents and drain valves with O-ring seals and hose barb connections allow for easy process control. Other ease-of-use features include flow direction arrows and ribbed housing for easy gripping even with gloved hands.

The Right Connections

Self-contained and disposable, Opticap® XL and XLT capsule filters are supplied with a choice of inlet and outlet connections to optimize your filtration process, including sanitary flanges which provide a high flow rate and hose barb.

Proven Integrity

Each capsule is integrity tested during the manufacturing process to ensure reliable performance in your process.

Robust Construction

Opticap® XL and XLT's capsule design allows unparalleled thermal and hydraulic stress resistance in a disposable filter, resulting in reliability, high confi-dence in the sterilization process, and improved cleanliness.

Opticap® XL 10 Capsule Filters

Opticap® XL disposable capsule filters with Viresolve® NFP membrane and patented capsule design minimize hold-up volume and reduce production losses.

Opticap® XLT 10, 20 and 30 Capsule Filters

Opticap® XLT disposable T-line capsule filters with Viresolve® NFP membrane offer a T-line design that accommodates series or parallel filtration to match your application needs, and a specially-designed patented stand enables quick and easy integration of Opticap® XLT capsules into your existing process.

Specifications

Viresolve® NFP Filter

	OptiScale®-25	10-inch Cartridge	20-inch Cartridge	30-inch Cartridge
Nominal Dimensions				
Length:	2.2 cm (0.87 in.)	30 cm (12 in.)	56 cm (22 in.)	81 cm (32 in.)
Effective Filtration Area	3.5 cm^2 (0.54 $in.^2$)	0.42 m^2 (4.5 ft^2)	0.84 m^2 (9.0 ft^2)	1.26 m^2 (13.6 ft^2)
Materials of Construction				
Membrane:	Modified PVDF	Modified PVDF		
O-ring:	–	Silicone		
Cage, core support:	–	Polypropylene		
Capsule housing:	PVDF	–		
Standard Connections	Female Luer-Lok™, male luer slip fittings	Code 7 (2-226) O-ring, bayonet with spear		
Maximum Operating Line Pressure (at 25 °C)	5.5 bar (80 psi)	5.5 bar (80 psi)		
Maximum Differential Pressure (at 25 °C)				
Forward:	5.5 bar (80 psi)	5.5 bar (80 psi)		
Reverse:	0.7 bar (10 psi)	3.4 bar (50 psi)		
Autoclaving	Water wet filter for 5 minutes at 3.4 bar (50 psi), liquid cycle, slow exhaust, at 123 °C maximum for 60 minutes.			
Bacteriophage Retention	Lot release testing on samples exhibited ≥ 4 LRV for ϕX174 (28 nm) at a challenge of 10^7 pfu/cm^2.			
Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) test.			
Non-fiber Releasing	Component materials meet criteria for a "non fiber releasing" filter as defined in 21 CFR 210.3 (b)(6).			
Component Materials Toxicity	Component materials were tested and meet the criteria of USP <88> Reactivity Test for Class VI Plastics. This product meets the requirements of the USP <88> Safety Test utilizing a 0.9% sodium chloride extraction.			
Integrity Test Specification	–	Air/water diffusion rates at 23 °C, 3.4 bar (50 psi):		
		≤ 10.0 cc/min	≤ 20.0 cc/min	≤ 30.0 cc/min
Wetting/Flushing	Water wet for 5 minutes at 3.4 bar (50 psi), or water wet at a minimum of 2.1 bar (30 psi) for 75 L/m^2			
Good Manufacturing Practices	These products are manufactured in a facility which adheres to FDA Good Manfacturing Practices.			

Specifications

Viresolve® Prefilters

	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.			

Specifications

Viresolve® NFP Filter

	Opticap® XL 10	Opticap® XLT 10	Opticap® XLT 20	Opticap® XLT 30
Nominal Dimensions				
Length:	34 cm (13 in.)	38 cm (15 in.)	62 cm (25 in.)	87 cm (34 in.)
Sanitary flange to sanitary flange:	–	15 cm (6.0 in.)	15 cm (6.0 in.)	15 cm (6.0 in.)
Sanitary flange to hose barb:	–	18 cm (6.9 in.)	18 cm (6.9 in.)	18 cm (6.9 in.)
Hose barb to hose barb:	–	20 cm (7.8 in.)	20 cm (7.8 in.)	20 cm (7.8 in.)
Effective Filtration Area	0.42 m^2 (4.5 ft^2)	0.42 m^2 (4.5 ft^2)	0.84 m^2 (9.0 ft^2)	1.26 m^2 (13.6 ft^2)
Materials of Construction				
Filter membrane:	Modified PVDF	Modified PVDF		
Film edge:	Polypropylene	Polypropylene		
Supports:	Polypropylene	Polypropylene		
Structural components*:	Polypropylene	Polypropylene		
Vent O-rings:	Silicone	Silicone		
Standard Connections	$^9/_{16}$ in. Hose barb	$^5/_8$ in. Hose barb		
	1½ in. Sanitary flange	1½ in. Sanitary flange		
Vent/Drain	¼ in. hose barb with double O-ring seal	¼ in. hose barb with double O-ring seal		
Maximum Operating Line Pressure (at 23 °C)	5.5 bar (80 psi)	5.5 bar (80 psi)		
Maximum Differential Pressure (at 25 °C)				
Forward:	5.5 bar (80 psid)	5.5 bar (80 psi)		
Reverse:	3.4 bar (50 psid)	3.4 bar (50 psid)		
Autoclaving	Water wet filter for 5 minutes at 3.4 bar (50 psi), liquid cycle, slow exhaust, at 123 °C maximum for 60 minutes.			
Bacteriophage Retention	Lot release testing on samples exhibited ≥ 4 LRV for ϕX174 (28 nm) at a challenge of 10^7 pfu/cm^2.			
Bacterial Endotoxin	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) test.			
Non-fiber Releasing	Component materials meet criteria for a "non fiber releasing" filter as defined in 21 CFR 210.3 (b)(6).			
Component Materials Toxicity	Component materials were tested and meet the criteria of USP <88> Reactivity Test for Class VI Plastics. This product meets the requirements of the USP <88> Safety Test utilizing a 0.9% sodium chloride extraction.			
TOC/Conductivity	Lot release testing on effluent exhibited less than 500 ppb TOC and conductivity less than 1.3 µS/cm after autoclaving and a water flush of:			
	12 L at 25 °C	12 L at 25 °C	24 L at 25 °C	36 L at 25 °C
Integrity Test Specification	Air/water diffusion rates at 23 °C, 3.4 bar (50 psi):			
	≤ 10.0 cc/min	≤ 10.0 cc/min	≤ 20.0 cc/min	≤ 30.0 cc/min
Wetting/Flushing	Water wet for 5 minutes at 3.4 bar (50 psi), or water wet at a minimum of 2.1 bar (30 psi) for 75 L/m^2			
Good Manufacturing Practices	These products are manufactured in a facility which adheres to FDA Good Manfacturing Practices.			

Specifications

Viresolve® Prefilters

	OptiScale®-40	0.11 m^2 Pod	0.55 m^2 Pod	1.1 m^2 Pod
TOC/Conductivity	–	Lot release testing on effluent exhibited TOC <4 ppm and conductivity <10 µS/cm after 3 autoclave cycles and a water flush of 100 L/m^2.		
Metals	–	Lot release testing on effluent exhibited the following values: 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 by the Limulus Amebocyte Lysate (LAL) test.			
Component Material Toxicity	Component materials were tested and meet the criteria of the USP <88> Reactivity Test for Class VI Plastics. Viresolve® Prefilters meet the requirements of the USP <88> Safety Test, utilizing a 0.9% sodium chloride extraction.			
Indirect Food Additive Quality Standard	All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177–182. These products are manufactured in accordance with a Quality Management System that is approved by an accredited registering body to the appropriate ISO® 9000 Quality Systems Standard.			

Ordering Information

Viresolve® NFP Filters

Device	Typical Processing Volume	Connections	Qty/Pk	Catalogue No.
OptiScale®-25 Capsule Evaluation Kit, 3 Membrane Lots	70 mL	Female Luer-Lok™, male luer slip fittings	3 x 3 (9)	SVPV A25 NB9
OptiScale®-25 Capsule Evaluation Kit, Single Membrane Lot	70 mL	Female Luer-Lok™, male luer slip fittings	9	SVPV SML NB9
Low Hold Up Volume Vmax™ Test Kit		For use with OptiScale®-25 devices	1	VIRUSVMAX
Opticap® XL 10 Capsule	250 L	1½ in. sanitary flange inlet and outlet	1	KVPV A10T T1
		$^{9}/_{16}$ in. hose barb inlet and outlet	1	KVPV A10H H1
		1½ in. sanitary flange inlet; $^{9}/_{16}$ in. hose barb outlet	1	KVPV A10T H1
Opticap® XLT 10 Capsule	250 L	1½ in. sanitary flange inlet and outlet	1	KVPV A1TT T1
		$^{5}/_{8}$ in. hose barb inlet and outlet	1	KVPV A1TH H1
		1½ in. sanitary flange inlet; $^{5}/_{8}$ in. hose barb outlet	1	KVPV A1TT H1
Opticap® XLT 20 Capsule	500 L	1½ in. sanitary flange inlet and outlet	1	KVPV A2TT T1
		$^{5}/_{8}$ in. hose barb inlet and outlet	1	KVPV A2TH H1
		1½ in. sanitary flange inlet; $^{5}/_{8}$ in. hose barb outlet	1	KVPV A2TT H1
Opticap® XLT 30 Capsule	750 L	1½ in. sanitary flange inlet and outlet	1	KVPV A3TT T1
		$^{5}/_{8}$ in. hose barb inlet and outlet	1	KVPV A3TH H1
		1½ in. sanitary flange inlet; $^{5}/_{8}$ in. hose barb outlet	1	KVPV A3TT H1
10 in. Cartridge Filter	250 L	Code 7 (2-226) O-ring bayonet with spear	1	CVPV 71T P1
20 in. Cartridge Filter	500 L	Code 7 (2-226) O-ring bayonet with spear	1	CVPV 72T P1
30 in. Cartridge Filter	750 L	Code 7 (2-226) O-ring bayonet with spear	1	CVPV 73T P1
Standard Opticap® XLT Capsule Stand			1	XLTS TAN D1

Viresolve® Prefilters

Device	Process Volume	Connections	Qty/Pk	Catalogue 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 1½ in. TC inlet and outlet	1	MSPV 01 FS1
0.55 m^2 Pod Filter	100 – 200 L	Disposable 1½ in. TC inlet and outlet	1	MSPV 05 FS1
1.1 m^2 Pod Filter	200 – 400 L	Disposable 1½ in. TC inlet and outlet	1	MSPV 10 FS1

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