Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Data Sheet

Viresolve® NFR Filters

Fast, Reliable Retrovirus Removal

Viresolve® NFR filters are designed for downstream purification and efficiently remove retroviruses, and other large virus contaminants from bioprocessing feed streams. The asymmetric polyethersulfone (PES) membrane is characterized by high flow rates and high protein recovery. Viresolve® NFR filters effectively trap large viruses and provide excellent clearance of large viral contaminants. These filters are available as OptiScale®-25 capsules for filter sizing studies, and both capsule and cartridge formats for pilot and large-scale manufacturing needs.

Viresolve® NFR filters protect downstream processes and improve product safety.

Fast, Reliable Clearance

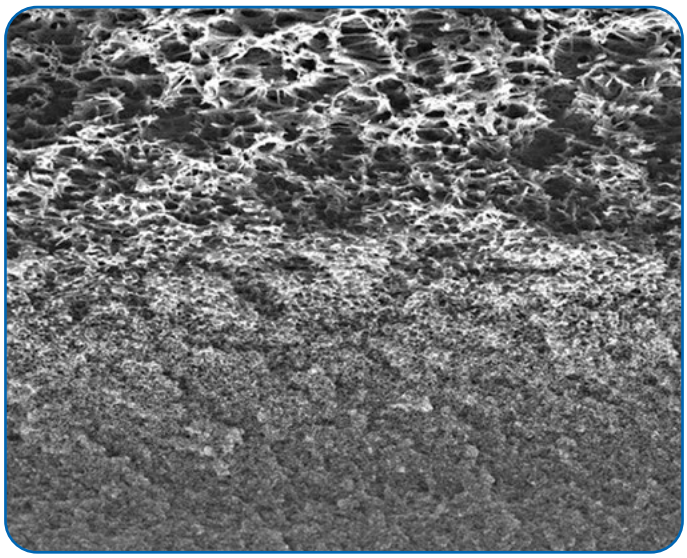
- ≥6 log removal of retroviruses
- >98% protein recovery
- Robust processing
- Fast alcohol-free integrity testing
- Each lot is 100% integrity tested

Filter Formats

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

Quality Management System

All Viresolve® NFR filters are designed, developed, and manufactured in accordance with a Quality Management System approved by an accredited registering body to ISO 9001 standards. Viresolve® NFR capsules and cartridge filters are integrity tested during manufacturing and are supported by a Validation Guide.



Viresolve® NFR filter's asymmetric membrane provides fast flow and unmatched retention of large virus.

Fast Integrity Testing

A convenient, easy to perform, air-water diffusion integrity test confirms the virus retention properties of the membrane.

Virus Retention

Viresolve® NFR cartridge and capsule filters have been extensively tested using a surrogate for retrovirus, bacteriophage Phi 6 (Φ6), 78 nm diameter. Challenge studies demonstrate consistent retention over a broad range of feed and processing conditions, Table 2.

Figure 1 highlights retention of large viruses with Viresolve® NFR filters.

Condition	Range
pH	4.5–8.5
Ionic Strength	25–250 mM
Process time	up to 4 hrs
Pressure	0.3–4.1 bar (5–60 psi)
Protein concentration	0–25 g/L

Table 2. Feedstock and Processing Conditions for >6.5 LRV Virus Retention Using Viresolve® NFR Filters

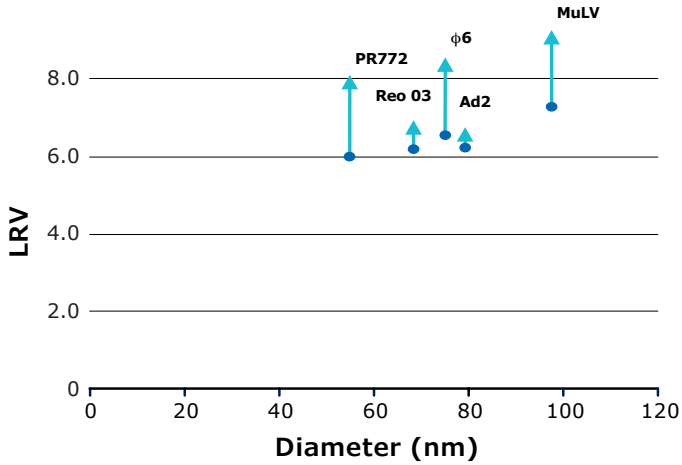


Figure 1. Representative Virus Retention Data for Viresolve® NFR Filters

Specifications

	OptiScale®-25	10-inch Cartridge	20-inch Cartridge	30-inch Cartridge
Materials of Construction Filter membrane: O-ring: Cage, core, end caps, non-woven supports, film edge: Cap and base:	Polyethersulfone Silicone — Acrylic	Polyethersulfone Silicone Polypropylene N/A		
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)	4.1 bar (60 psi)	5.5 bar (80 psi)		
Maximum Differential Pressure (at 25 °C) Forward: Reverse:	 4.1 bar (60 psi) 0.7 bar (10 psi)	 5.5 bar (80 psi) 3.4 bar (50 psi)		
Wetting/Flushing	Water wet filter for 10 min at 2 bar (30 psi) or for 5 min at 3.4 bar (50 psi) to a volume of 75 L/m^2.			
Autoclaving	Not autoclavable. Sold gamma irradiated	After wetting, may be autoclaved for 3 cycles of up to 60 min at 125 °C, using liquid cycle, slow exhaust. May be steamed-in-place for 30 minutes at 125 °C.		
Non-volatile Residue (NVR)[1]	—	Extractables level after a 10 min 1.5 Lpm/ft^2 flush, after 24 hrs in ASTM® Type 1 reagent-grade water at controlled room temperature:		
		≤35 mg	≤70 mg	≤105 mg
Bacteriophage Retention[1]	Lot release testing on samples exhibited ≥6 LRV for Φ6 (78 nm).			
Bacterial Endotoxin[1]	Aqueous extraction contains < 0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) test. This meets the requirements of USP <85>.			
Non-fiber Releasing[1]	Component materials meet criteria for a “non fiber releasing” filter as defined in 21 CFR 210.3 (b)(6).			
Oxidizable Substances[1]	—	Meet the requirements of the USP Oxidizable Substances Test after a water flush of:		
		4,000 mL	8,000 mL	12,000 mL
Component Materials Toxicity[1]	Component materials were tested and meet the criteria of USP <88> Reactivity Test Class VI Plastics, and are non-toxic per the USP <88> Reactivity Safety Test.			
Integrity Test Specification[1]	—	Air/water diffusion rates at 23 °C, 3.4 bar (50 psi):		
		≤23 cc/min	≤46 cc/min	≤698 cc/min
Thermal and Hydraulic Stress[1]	—	Lot release testing on autoclaved samples at 25 °C exhibited integrity after a forward stress to 80 psid (5.5 bar) and a reverse stress to 50 psid (3.4 bar).		
Quality Management System	These products are manufactured in a facility which is certified to ISO 9001:2015 Quality Management Systems.			

[1] A Certificate of Quality validating these specification is included with every shipment.

	Opticap® XL 10	Opticap® XLT 10	Opticap® XLT 20	Opticap® XLT 30
Materials of Construction Filter membrane: Cage, core, end caps, non-woven supports, film edge, capsule housing: Vent O-rings:	 Polyethersulfone Polypropylene Silicone			
Standard Connections	1 1/2 in Sanitary flange			
Vent/Drain	1/4 in Hose barb with double O-ring seal			
Maximum Operating Line Pressure (at 25 °C)	5.5 bar (80 psi)			
Maximum Differential Pressure (at 25 °C) Forward: Reverse:	 5.5 bar (80 psi) 3.4 bar (50 psi)			
Wetting/Flushing	Water wet filter for 10 min at 2 bar (30 psi) or for 5 min at 3.4 bar (50 psi) to a volume of 75 L/m^2.			
Autoclaving	After wetting, may be autoclaved for 3 cycles of up to 60 min at 125 °C, using liquid cycle, slow exhaust.			
Non-volatile Residue (NVR)[1]	Extractables level after a 10 min 1.5 Lpm/ft^2 flush, after 24 hrs in ASTM® Type 1 reagent-grade water at controlled room temperature:			
	≤35 mg	≤35 mg	≤70 mg	≤105 mg
Bacteriophage Retention[1]	Lot release testing on samples exhibited ≥6 LRV for Φ6 (78 nm).			
Bacterial Endotoxin[1]	Aqueous extraction contains <0.5 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) test. This meets the requirements of USP <85>.			
Non-fiber Releasing[1]	Component materials meet criteria for a “non fiber releasing” filter as defined in 21 CFR 210.3 (b)(6).			
Oxidizable Substances[1]	Meet the requirements of the USP Oxidizable Substances Test after a water flush of:			
	4,000 mL	4,000 mL	8,000 mL	12,000 mL
Component Materials Toxicity[1]	Component materials were tested and meet the criteria of USP <88> Reactivity Test Class VI Plastics. This product meets the requirements of the USP <88> Safety Test utilizing a 0.9% sodium chloride extraction.			
Integrity Test Specification[1]	Air/water diffusion rates at 23 °C, 3.4 bar (50 psi):			
	≤23 cc/min	≤23 cc/min	≤46 cc/mi	≤69 cc/min
Thermal and Hydraulic Stress[1]	Lot release testing on autoclaved samples at 25 °C exhibited integrity after a forward stress to 80 psid (5.5 bar) and a reverse stress to 50 psid (3.4 bar).			
Quality Management System	These products are manufactured in a facility which is certified to ISO 9001:2015 Quality Management Systems.			

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Sizing Guidelines

Device	Effective Filtration Area	Typical Processing Volume	Length	Typical Hold-up Volume*
OptiScale®-25 Capsule	3.5 cm^2 (0.54 in^2)	0.165 L	2.2 cm (0.87 in)	1 mL
10 inch Cartridge Filter	0.43 m^2 (4.6 ft^2)	600–1,200 L	30.5 cm (12 in)	175 mL
20 inch Cartridge Filter	0.854 m^2 (9.2 ft^2)	1,200–2,400 L	60.5 cm (22 in)	325 mL
30 inch Cartridge Filter	1.281 m^2 (13.8 ft^2)	1,800–3,600 L	86.6 cm (31.5 in)	490 mL
Opticap® XL 10 Capsule	0.43 m^2 (4.6 ft^2)	600–1,200 L	34 cm (13 in)	175 mL
Opticap® XLT 10 Capsule	0.43 m^2 (4.6 ft^2)	600–1,200 L	38 cm (15 in)	175 mL
Opticap® XLT 20 Capsule	0.854 m^2 (9.2 ft^2)	1,200–2,400 L	62 cm (25 in)	325 mL
Opticap® XLT 30 Capsule	1.281 m^2 (13.8 ft^2)	1,800–3,600 L	87 cm (34 in)	490 mL

* On filtrate side, after 1 minute of 20 psi upstream air pressurization.

Ordering Information

Device	Connections	Qty/Pk	Catalogue No.
OptiScale®-25 Capsule Evaluation Kit, 3 Membrane Lots	Female Luer-Lok™, male luer slip fittings	3 x 3 (9)	SZRV025NB9
OptiScale®-25 Capsule Evaluation Kit, Single Membrane Lot	Female Luer-Lok™, male luer slip fittings	9	SZRVSMLNB9
Low Hold Up Volume Vmax™ Test Kit	For use with OptiScale®-25 devices	1	VIRUSVMAX
10 inch Cartridge Filter	Code 7 (2-226) O-ring bayonet with spear	1	CZRV71TP1
20 inch Cartridge Filter	Code 7 (2-226) O-ring bayonet with spear	1	CZRV72TP1
30 inch Cartridge Filter	Code 7 (2-226) O-ring bayonet with spear	1	CZRV73TP1
Opticap® XL 10 Capsule	$1^1/_2$ in Sanitary flange inlet and outlet	1	KZRVA10TT1
Opticap® XLT 10 Capsule	$1^1/_2$ in Sanitary flange inlet and outlet	1	KZRVA1TTT1
Opticap® XLT 20 Capsule	$1^1/_2$ in Sanitary flange inlet and outlet	1	KZRVA2TTT1
Opticap® XLT 30 Capsule	$1^1/_2$ in Sanitary flange inlet and outlet	1	KZRVA3TTT1
Standard Opticap® XLT Capsule Stand		1	XLTSTAND1

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