

Ultipor VF Grade DV50

VIRUS FILTER CARTRIDGES

Our Ultipor VF grade DV50 filter cartridges feature hydrophilic polyvinylidene fluoride (PVDF) microporous membranes to remove significant levels of viruses from biological solutions, while enabling > 95% transmission of proteins up to 300 kD or larger. Ultipor VF filters achieve practical flows and pressure drops while effectively removing nanometer-size viral contaminants with high protein yields.

Ultipor DV50 filters are particularly suited for enhanced viral safety of viral vector therapy manufacturing where 20 nm virus filters are not suitable.

Key features

- Sanitary direct flow cartridges
- Robust size exclusion mechanism
- ≥ 6 log TR for > 50 nm viruses ¹
- Low binding for high protein yields
- High transmission of albumin and immunoglobulin G (IgG)
- Very low extractables
- Autoclavable and steamable *in situ* (steam-in-place [SIP])
- 100% integrity tested (correlated to virus retention)
- Manufactured for use in conformance with current good manufacturing practice (cGMP)
- Pharmaceutical 'P' optimized with certificate of test provided

¹ Claims based on challenges with bacteriophage – bacterial viruses PR772 (53 nm), T1 (50 × 150 nm) in different carrier fluids, like MEM+10% FBS, Gelatin (0.1%), phosphate, saline (0.9%).

High quality standards

- Non-fiber-releasing per Code of Federal Regulations (CFR) Title 21

Biological tests:

- Meets United States Pharmacopeia (USP) biological reactivity, *in vivo*, for class VI-121°C plastics



Fig 1. Ultipor DV50 filter cartridge and Kleenpak Nova capsule.

Effluent quality tests (P tests) ²

- Meets cleanliness per USP particulates in injectables
- Non-pyrogenic per USP bacterial endotoxins (<0.25 EU/mL)
- Meets total organic carbon and conductivity per USP purified water, pH per USP packaged waters

² Confirmed for each filter lot

Ultipor VF grade DV50 filters

IN SBF JUNIOR CARTRIDGES

Technical specifications

Materials of construction

Membrane	Hydrophilic modified PVDF
Support and drainage layers	Polyester
Core, cage and end caps	Polypropylene (PP)
O-rings	Silicone

Operating conditions

Maximum differential pressure	3 bard (43.5 psid)
Recommended operating pressure	1–2 bard (15–29 psid)
Maximum differential pressure for integrity test performance (short-term)	6.0 bard (90 psid)
Recommended operating delta pressure (dP)	< 30 psi
Maximum differential pressure	6.2 bar (90 psi) during integrity testing 3.1 bar (45 psi) for continuous service 0.3 bar (4 psi) during steam sterilization

Autoclave/steaming

Autoclavable or steamable <i>in situ</i> for up to 3 cycles	Maximum temperature 125°C
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Aqueous extractables (NVR)

1 mg per element in deionized water at 20°C–25°C after autoclaving
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Filtration area (nominal)

0.074 m ²

Nominal dimensions

Lengths	62 mm (2.4 in.)
Diameter	43 mm (1.7 in.)

Configuration

Single open-ended cartridge
Sanitary style plug adapter
Double 116 O-ring

Ordering information

Filter area	Product code
740 cm ²	SBF1DV50PH4

Ultipor VF grade DV50 filters

IN AB CARTRIDGES

Technical specifications

Materials of construction

Membrane	Hydrophilic modified PVDF
Support and drainage layers	Polyester
Core, cage and end caps	PP
Code 7 adapter	PP with encapsulated stainless steel reinforcing ring
O-rings	Silicone

Configuration (AB code 7)

Double 226 O-ring adapter, fin end with bayonet lock
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Nominal dimensions

Lengths	10 in. (254 mm), 20 in. (508 mm), 30 in. (762 mm)
Diameter	70 mm (2.75 in.)

Operating conditions

Maximum differential pressure	3 bard (43.5 psid)
Recommended operating pressure	1–2 bard (15–29 psid)
Maximum differential pressure for integrity test performance (short-term)	6.0 bard (90 psid)

Sterilization

Autoclavable or steamable <i>in situ</i> for up to 3 cycles	Maximum temperature 125°C
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Aqueous extractables (NVR)

< 5 mg per 254 mm element, process-ready (after integrity testing in 30% IPA/water, water flush, and autoclaving)

Filtration area (nominal)

1.6 m ² per 254 mm (10 in.) element
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Flow rate/differential pressure

Minimum flow of 1 L/min at 3 psid per 254 mm (10 in.) element for filtered water
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Ordering information

Length	Filter area	Product code
10 in.	1.6 m ²	AB1UDV507PH4
20 in.	3.2 m ²	AB2UDV507PH4
30 in.	4.8 m ²	AB3UDV507PH4

Ultipor VF grade DV50 filters

IN NOVASIP CARTRIDGES

Technical specifications

Materials of construction

Membrane	Hydrophilic modified PVDF
Support and drainage layers	Polyester
Core, cage and end caps	PP
Housing shell	Polyetherimide
O-rings	Silicone

Nominal dimensions

Length	157 mm (6.18 in.)
Diameter	123 mm (4.8 in.)
Nominal filter area	0.4 m ²
Inlet and outlet	26–38 mm (1–1½ in.) sanitary flange

Operating conditions

Recommended operating pressure	1–2 barg (15–29 psid)
Maximum differential pressure ³	3 barg (43.5 psid)

³ **Note:** Maximum assembly pressure is 6.0 barg (90 psid) for short-term integrity testing.

Sterilization

Autoclavable and steamable *in situ* for 3 × 1-hour cycles at up to 125°C (non-irradiated product only)

Gamma-irradiatable

Aqueous extractables (NVR)

< 5 mg/capsule (deionized water at 20°C)

Flow rate/differential pressure

0.3 L/min at 2 bar (29 psi)

Ordering information

Filter area	Product code
4000 cm ²	CL3DV50P1

Ultipor VF grade DV50 filters

IN KLEENPAK™ NOVA CAPSULES

Technical specifications

Materials of construction

Membrane	Hydrophilic modified PVDF
Drainage layers	PP
Support, drainage, core, cage, end caps	PP
Housing bowl	PP
Housing head ¹	PP
O-rings	Silicone elastomer

Nominal dimensions

T-style capsules	NT6	NT7	NT8
Maximum diameter (including valves)	240 mm	240 mm	240 mm
Length	349 mm	598 mm	848 mm
Inline style capsules	NP6	NP7	NP8
Maximum diameter (including valves)	154 mm (6.1 in.)	154 mm (6.1 in.)	154 mm (6.1 in.)
Length with hose barb inlet and outlet	397 mm (15.6 in.)	644 mm (25.4 in.)	895 mm (35.2 in.)
Length with sanitary inlet and outlet	335 mm (13.2 in.)	584 mm (23.5 in.)	834 mm (32.8 in.)

Operating parameters⁴

Maximum operating temperature	40°C
Maximum operating pressure	3 barg (43.5 psig) at 40°C

⁴ With compatible fluids which do not soften, swell or adversely affect the product or its materials of construction.

Sterilization

Autoclave (maximum)	Single-cycle, 3 × 20 minutes 135°C, for 1 hour
Gamma irradiation	Maximum dosage: 50 kGy



Ultipor VF grade DV50 filters

IN KLEENPAK™ NOVA CAPSULES

Ordering information

Inlet/outlet connections	Style	Length	Filter area	Sterilization options	Product code
25–38 mm (1–1½ in.) sanitary flange inlet and outlet	Inline	10 in.	1.6 m ²	Autoclavable	NP6LUDV50P1
				Suitable for gamma irradiation	NP6LUDV50P1G
		20 in.	3.2 m ²	Autoclavable	NP7LUDV50P1
		30 in.	4.8 m ²	Autoclavable	NP8LUDV50P1
	T-style	10 in.	1.6 m ²	Autoclavable	NT6UDV50P1
				Presterilized	NT6UDV50P1B1S
				Suitable for gamma irradiation	NT6UDV50P1G
		20 in.	3.2 m ²	Autoclavable	NT7UDV50P1
				Suitable for gamma irradiation	NT7UDV50P1B1G
		30 in.	4.8 m ²	Autoclavable	NT8UDV50P1
				Suitable for gamma irradiation	NT8UDV50P1G

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