



Pegasus™ SV4 Virus Removal Filter Cartridges



Constant, stable flow-rate performance filters combining efficient, high viral clearance with significantly-reduced processing costs

Features

- Incorporates Pegasus SV4 virus filter membrane
- Demonstrates constant, stable flow-rate performance
- Highly-resistant to filter 'plugging'
- High filter area per cartridge
- Automated in-situ integrity test both pre-use and post-use
- Can be cleaned-in-place (CIP) and steamed-in place (SIP)
- Rigorous quality testing at multiple stages of production
- Suitable for inclusion in Pall's fully-automated virus filtration systems

Benefits

- Offers robust, high parvovirus clearance (> 4 log reduction value)
- Improves process and cost control, enables maximum virus filtration economy and efficiency
- Shows outstanding throughput capacity in both dilute and complex/concentrated biological fluids
- Minimizes hold-up volume and system space requirements, reducing Cost Of Goods Sold (COGS)
- Provides easy, reliable integrity testing, reducing labor costs and minimizing the risk of handling errors
- Ensures the highest aseptic safety
- Assures consistent performance as per the specification
- Enables the highest level of process control and safety

Description

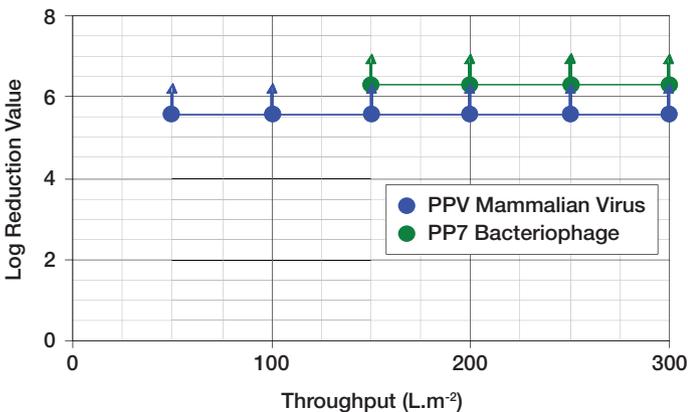
With the ever-present risk of virus contamination in biologic products, potential sources of virus contamination of biotechnology products include viruses associated with cell lines (endogenous viruses), or viruses introduced into the cell line or product from culture medium or during the production process (adventitious viruses). Viruses could also potentially be present in donations for plasma derivatives. Pegasus SV4 Virus Removal Filter Cartridges are direct flow filters combining robust, high viral clearance of parvovirus and larger viruses with high throughput capacity and demonstrating constant, stable flow-rates in both dilute and complex/concentrated biological fluids. Such consistent, constant flow rates and outstanding throughput performance allows a very high degree of process control.

High Parvovirus Clearance

Pegasus SV4 Virus Removal Filter Cartridges demonstrate highly-efficient clearance of both small 'non-enveloped' viruses as well as large viruses. Figure 1 provides an example of its high parvovirus clearance by showing the typical performance of a Pegasus SV4 filter in a 1 g.L⁻¹ BSA solution, as per the PDA's guidelines:

Figure 1

Retention of porcine parvovirus (PPV, n=4) and small spherical bacteriophage virus (PP7, n=9) by Pegasus Grade SV4 virus membrane in 1 g.L⁻¹ BSA at 3.1 bar (45 psi)¹



¹ PPV retention testing carried out at an independent virus validation test laboratory using 47 mm filter discs

Due to its resistance to flux decay and outstanding throughput properties, typical spikes will not have significant impact on the flux decay of Pegasus SV4 Virus Removal Filter Cartridges.

Constant, Stable Flow-Rate Performance with Outstanding Throughput Capacity

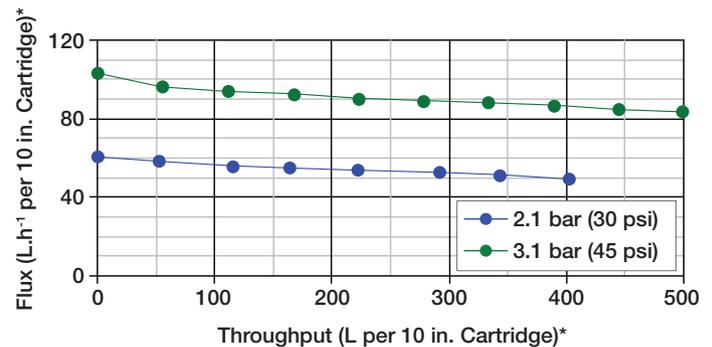
With the need to control the Cost Of Goods Sold being one of the main points of consideration in downstream processing, Pegasus SV4 Virus Removal Filter membrane has been designed to address this need by offering constant, stable flow-rate performance and outstanding throughput capacity, thereby improving process and cost control and enabling maximum virus filtration economy and efficiency.

Highly-Efficient and Economical

Pegasus SV4 Virus Filter membrane also demonstrates highly-efficient clearance of both small 'non-enveloped' viruses and large viruses, even showing constant, stable flow-rate performance when used with dilute or complex/concentrated biological fluids. It also offers stable pressure/flux capability in more complex or concentrated feeds, helping to improve virus filtration economy in highly-concentrated protein solutions. Figure 2 shows a typical flux profile for Pegasus SV4 Virus Removal Filter Cartridges when challenged with a monoclonal antibody solution.

Figure 2

Results of Filterability Tests at 2.1 bar (30 psi) or 3.1 bar (45 psi) with up to 25 g.L⁻¹ (2.5%) MAb



*Performance predicted from tests performed on Pegasus SV4 Virus Removal Filter Discs (47 mm)

Reduces Processing Costs

Pegasus SV4 Virus Removal Filter Cartridges offer a very high filter area per cartridge (2.25 m²) due to their unique, patented laid-over pleat construction which enables significantly more filter membrane to be packed into each cartridge. This helps to maximize process productivity while minimizing process costs, by reducing the amount of filter cartridges required per installation, and helps minimize the hold-up volume of the virus filter system.

Figure 3
Laid-over pleat construction utilized by Pegasus SV4 Virus Removal Filter Cartridges



Superior Process Control and Safety

Pegasus SV4 Virus Removal Filter Cartridges offer the highest level of process control and safety in process-scale virus filtration.

Process Requirement: Aseptic Safety

Best practice – Pegasus SV4 Virus Removal Filter Cartridges can be cleaned-in-place (CIP) and steamed-in place (SIP) and are suitable for inclusion into available fully-automated systems.

Process Requirement: Easy, Reliable Integrity Testing

Best practice – Pegasus SV4 Virus Removal Filter Cartridges can be in-situ integrity tested both pre-use and post-use.

Table 1
Integrity Testing of Pegasus SV4 Virus Removal Filter Cartridges

Pegasus SV4 Virus Removal Filter Cartridges

Steam In Place (SIP)	Yes
Autoclavable By User	Yes
Integrity Test Pre-Use	Yes (Non destructive, water-wet in situ)
Integrity Test Post-Use	Yes (Non destructive, water-wet in situ)

Figure 4
Integrity Testing Pegasus SV4 Virus Removal Filter Cartridges with a Palltronic® Flowstar Filter Integrity Test Instrument



Suitable for Inclusion in Pall's Fully-Automated Virus Filtration Systems

Pall also offers fully-automated virus filtration systems that enable precise and consistent operation, together with improved process efficiency. The systems can be designed with steam-in-place (SIP), clean-in-place (CIP) and integrity-test-in-place (ITIP) capabilities. The Cluster-Filtration technology assures maximum filter integrity sensitivity. Pall's range of fully automated virus filtration systems ensures the highest level of manufacturing safety and process performance.

Figure 5
Typical Pall Fully-Automated Virus Filtration System



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Rigorous Quality Testing at Multiple Stages of Production

Throughout the process of manufacture of Pegasus SV4 Virus Removal Filter Cartridges, Pall's rigorous quality control systems ensure consistent performance as per the product specification.

- ▶ Quality Control at Multiple Production Stages
- ▶ 100% fabrication integrity tested – correlated to PP7 bacteriophage removal
- ▶ Viral reduction tested with PP7 bacteriophage lot release test
- ▶ 100% fabrication water flow tested
- ▶ Protein transmission tested
- ▶ Visual inspection control

Full Traceability, Fast and Efficient Data Entry

Each Pegasus SV4 Virus Removal Filter Cartridge is manufactured under a Quality Management System certified to ISO 9001:2008, and is easily identified by part number, lot number and a unique serial number, which are laser-marked on the filter cartridge as a two-dimensional (2D) barcode. These codes can be read by a barcode reader, enabling complete traceability of the manufacturing history.

Figure 6

Pegasus SV4 Virus Removal Filter Cartridge showing 2D barcode



Figure 7

Scanning a barcode on a Pegasus SV4 Virus Removal Filter Cartridge using a Palltronic Barcode Reader and Palltronic Flowstar IV Filter Integrity Test Instrument



High Quality Standards

The filter components have met the requirements for biological reactivity, in vivo, under USP <88> (for Class VI – 121 °C plastics) and in vitro, under USP <87> (Elution Test).

- ▶ Meets Cleanliness per USP <788> Particulate Matter in Injections
- ▶ Non-Fiber-Releasing per Title 21 of the U.S Code of Federal Regulations (CFR) parts 211.72 and 210.3 (b) (6)
- ▶ Non-Pyrogenic per USP <85> Bacterial Endotoxins Test

The filter cartridge does not contain materials of construction that are considered specified TSE or BSE-risk materials according to current legislation and guidelines (reference European CPMP EMA/410/01 and U.S. Code of Federal Regulations, Title 21 Part 189.5).

Scientific and Laboratory Services

Pall's Scientific and Laboratory Services (SLS) group is available worldwide to provide you with the scientific and technical support you need to mitigate risk as part of your viral safety strategy. Our scientists have extensive experience in filtration and chromatographic methods, validating processes developed to prevent virus contamination, and developing standard operating procedures for the correct operation of virus removal technology in unit operations. Our experience also covers the necessary skills and expertise to appropriately document the entire approach, from test protocols that include scientific rationale related to methodology and sampling, to test execution including data analysis, followed by scientific report generation ready-prepared for regulatory submission. Learn more at www.pall.com/services.

Technical Specifications

Item	Material of Construction
Membrane	Hydrophilic modified polyvinylidenedifluoride (PVDF)
Support and Drainage Layers	Polyester
Core, Cage and Endcaps	Polypropylene
Code 7 Adapter	Polypropylene with encapsulated stainless steel reinforcing ring
O-rings	Silicone

Operating Parameters*

Recommended Operating Differential Pressure	2.1 to 3.1 bard (30 to 45 psid)
Maximum Differential Pressure	3.1 bard (45 psid) for continuous service 0.3 bard (4.3 psid) during steam sterilization 6.2 bard (90 psid) during integrity testing only
Autoclave/Steaming	Autoclavable or steamable in-situ
Maximum Operating Temperature	40 °C (104 °F)

* In compatible fluids that do not soften or swell, or adversely affect the filter or its materials of construction. Contact Pall for recommended procedures to qualify filters under actual conditions of use.

Pore size	20 nm (nominal)
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Retention Ratings (Virus)	> 4 log reduction value for bacteriophage PP7 **†
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** Claims based on challenge with parvovirus model bacteriophage (bacterial virus) PP7

† > 4 log reduction value for bacteriophage PP7 per Parenteral Drug Association (PDA) Technical Report 41 rating method for small virus-retentive filters
> 4 log reduction value typically expected with mammalian parvoviruses

Aqueous Extractables (NVR)	Refer to Pall Publication USTR 2839
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Filter Area (Nominal)	2.25 m ² (24 ft ²) per 254 mm (10 in.) cartridge
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Forward Flow Integrity Test	Diffusional flow integrity test, carried out by standard upstream or downstream methods
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Table 2

Process Scale-Up with Pegasus Grade SV4 Virus Filters

Filter Type	Part Number	Filter Area
Pall Minidisc Capsule	10MCFV4	0.00096 m ²
Filter Disc (47 mm)	FTKSV4047	0.0011 m ² (in FTK200 Holder)
Mini Kleenpak™ Capsule	KA02SV42FT***	0.058 m ²
1 in. Kleenpak Nova Capsule	NP1LUSV4P1	0.25 m ²
10 in. Filter Cartridge	AB1USV47PH4	2.25 m ²
10 in. Kleenpak Nova Capsule (In-Line Style)	NP6LUSV4P1	2.25 m ²
10 in. Kleenpak Nova Capsule (T-Style)	NT6USV4P1	2.25 m ²

Not all filter types can be steam-sterilized. Consult individual product datasheets for technical specifications.

*** Filterability Tool version (FT). Not qualified for virus removal. For filterability tests only

Ordering Information

Item	Length (Nominal)	Part Number
Pegasus SV4 Virus Removal Filter Cartridge, Pall code 7 double o-ring, bayonet lock and fin	254 mm (10 in.)	AB1USV47PH4
Pegasus SV4 Virus Removal Filter Cartridge, Pall code 7 double o-ring, bayonet lock and fin	508 mm (20 in.)	AB2USV47PH4
Pegasus SV4 Virus Removal Filter Cartridge, Pall code 7 double o-ring, bayonet lock and fin	762 mm (30 in.)	AB3USV47PH4



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