



Pegasus™ Grade LV6 Virus Removal Filter Cartridges

#### **Description**

# Large Virus Removal Filter with High Flow Performance

The risk of large virus contamination is a common feature of biologic products. Potential sources of large virus contamination (retroviruses, for example) of biotechnology

products include viruses associated with the cell lines (endogenous viruses), or viruses introduced into the cell line or product during the production process (adventitious viruses).

Large viruses like HIV could potentially be present in donations for plasma derivatives. Pegasus Grade LV6 AB-style Filter Cartridges with Ultipleat® construction

provide an efficient and economical method for removing large viruses like Retroviruses with > 6 log titer reduction or larger virus antibody complexes from biological solutions. The unique Pegasus LV6 membrane in combination with the patented Ultipleat filter construction provides robust high flow rates and total throughput performance which minimizes process costs. The high filter area per filter cartridge reduces the required amount of filter elements per installation and minimizes the hold up volume of the virus filter system. The proven hydrophilic PVDF microporous membrane enables high transmission of proteins also for larger proteins. The filter is delivered pre-sterilized and prewetted which reduces handling time.

# **Features and Benefits**

- Robust virus retention
- > 6 log T<sub>R</sub> for large viruses
- High flow rate and total throughput performance
- High filter area per filter cartridge
- · Less filter elements per installation and minimized virus system hold up volume
- · Low binding for high protein yields
- High protein transmission
- Pre-sterilized and pre-wetted easy to use
- SIP and CIP able
- 100% integrity tested (correlated to virus retention)
- · Manufactured for use in conformance with cGMP
- Pharmaceutical P-optimized with Certificate of Test provided
- Validation Guide available

## **High Quality Standards**

- Non-Fiber-Releasing per 21 CFR
- Meets USP Biological Reactivity, in vivo, for Class VI-121 °C plastics
- 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

## **Specifications**

## **Materials Of Construction**

Membrane	Acrylate-modified polyvinylidene fluoride (PVDF)
Membrane Support and Drainage Layers	Polyethylene/polypropylene
Core and Endcaps	Polypropylene
Filter Cage	Polypropylene with encapsulated reinforcing ring
O-rings	Ethylene propylene

### **Operating Conditions**

Recommended Operating Differential Pressure	1 – 2 bar (14.5 – 29 psi differential)
Maximum Differential Pressure	4.1 bar (60 psi) during integrity testing
	3.1 bar (45 psi) for continuous service

0.3 bar (5 psi) during steam sterilization

#### Autoclave/Steaming<sup>1</sup>

Autoclavable or steamable in-situ for up to 3 cycles	Maximum Temperature 125 °C
<sup>1</sup> Contact Pall for recommended procedures to qualify filters under	er actual conditions of use.

## **Typical Aqueous Extractables (NVR)**

Out of Box, T0	Average 32 mg, Standard Deviation 3.6 mg
After autoclaving at 125 $^{\circ}$ C ± 5 $^{\circ}$ C	Average 56 mg, Standard Deviation 3.6 mg

#### Filter Area (Nominal)

1.65 m<sup>2</sup> (17.8 ft<sup>2</sup>) per 254 mm (10 in.) element

#### **Flow Rate/Differential Pressure**

12 L/min per 254 mm (10 in.) module Water Flow Rate at 2.1 bar (30 psi) differential pressure

## Forward Flow Integrity Test<sup>2</sup>

Diffusional flow integrity test, carried out by standard upstream or downstream methods Correlated to > 6 log  $T_R$  for 53 – 82nm PR772 phage<sup>3</sup> Test Wetting Fluid V Test Pressure 4

Water 4.150 bar (60 psi) (air test gas)† <sup>2</sup> Contact Pall for cartridge values and correlation data. Validation Guide available on request. Water or bufferwet values for installation confirmation can also be provided
<sup>3</sup> The Parenteral Drug Association virus filter task force has chosen PR772 as the model bacteriophage to standardize nomenclature for large-pore-size virus-retentive filters
† Bar value rounded up to nearest 0.025 bar

# Process Scale-up with Pegasus Grade LV6 Virus Filters

Part Number	Filter Area
FTKLV6 Filter Discs	11.1 cm <sup>2</sup> (0.012 ft <sup>2</sup> )
AB( )ULV67PJ	1.65 m (17.8 ft²) per 254 mm (10 in.)
Length Code: 1 = 254 mm (10 in.), 2 = 5	508 mm (20 in.), 3 = 762 mm (30 in.)

# Other Pall Direct Flow Virus Filters and Prefilters with Hydrophilic PVDF membrane

Membrane Type	Description
UDV50	> 6 Log T <sub>R</sub> for viruses > 50 nm
DV20	> 3 Log T <sub>R</sub> for viruses $>$ 20 nm
DVD	Sub 0.1 µm virus prefilter
DJL	0.1 μm (+ 0.2 μm prefilter layer)
DFL	0.2 µm (double-layer)
DBL	0.45 µm (+ 0.65 µm prefilter layer)

#### **Ordering Information**

lumber:		<b>P</b>		$\square$		P	
Code	Nominal Length	Code	Removal Rating	Code	Adapter	Code	Seal Material
1	254 mm (10 in.)	ULV6	≥ E Log TR for large viruses	7	Double 226 O-ring with bayonet lock and finned end	- 1	Ethylene propylene
2	508 mm (20 in.)					1	-
. 9	762 mm (30 in.)						

#### **Contact Information**

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This information is accurate as of the revision date indicated.