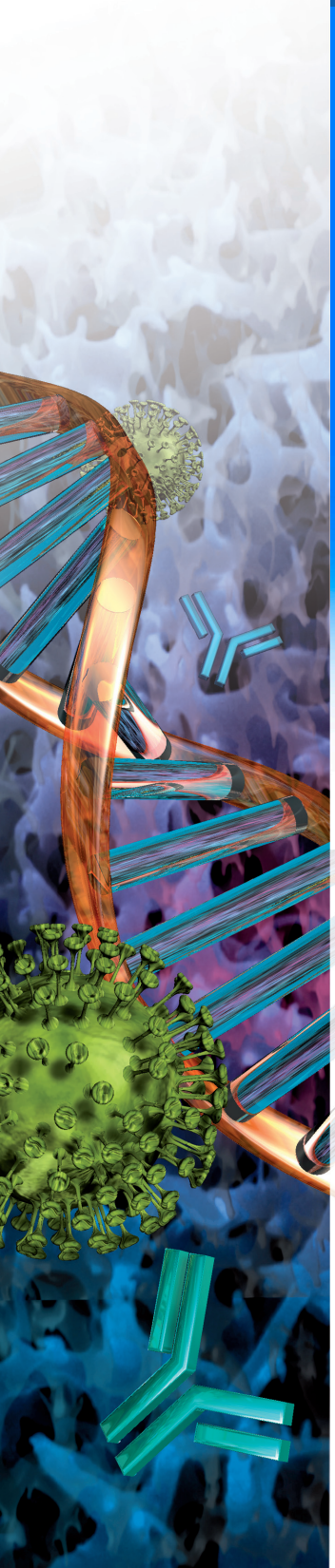
Life Sciences

USD3157c

Pall Kleenpak™ Nova Capsules and Cartridges with Pegasus™ Prime Virus Removal Filter Membrane



Process-Scale Virus Filtration

Pall Pegasus Prime virus membrane provides robust virus retention to protect critical manufacturing bioprocesses, assure drug quality and safeguard health. These gamma irradiated cartridges and capsules combine high flow and robust capacity, to simplify your process and deliver sustainable economy at all scales.

The flow, filter capacity and virus retention established during small scale filterability and virus validation studies scale to a range of products to support your process and offer the highest degree of manufacturing control, flexibility and security.

*Filtration. Separation. Solution.*SM

Features and Benefits

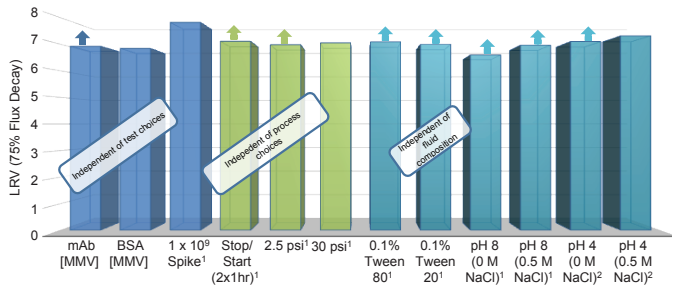
Robust high LRV, independent of process fluid or process parameters	Stable performance and assured patient safety in a broad process design space • Maximize process flexibility to minimize the risk of process deviations
Robust capacity and high flow	Small filtration footprints and short process times. • Economic processes and easy integration into automated processes
Gamma-irradiated, sterile and fully disposable	Ready to use. • No need for additional sterilisation or sanitisation procedures
Full scale-up range	Predictable performance at all scales • Simple process development
Full pre-filter scale-up range with consistent pre-filter to virus filter area ratios	Control scale-up risks • Faster, simplified scale-up
Water wet integrity testing	Easy to use • As simple to use as sterile filtration

Pegasus Prime virus filters deliver robust, high LRV independent of process parameters, process fluid and validation choices.

The data illustrated in Figure 1 demonstrate the reliable and stable performance across a wide range of process conditions and highlights process flexibility that makes Pegasus Prime virus filtration the ideal first choice virus filter for bioprocesses.

Figure 1

Robust, High Virus Retention



[1] *Tested using phage PP7*

[2] *Tested using phage ϕX174*

Pegasus Prime virus filters combine high LRV with high throughput and high flow in all mAb solutions to deliver an economic virus filtration solution with a small footprint for easy integration into single-use and automated processes.

The performance of three virus filtration options in a variety of fouling fluids is shown in Figure 2. These data illustrate that Pall's comprehensive virus filtration portfolio can minimize the number of virus filters required for any given process. The most common economic solutions are shown below.

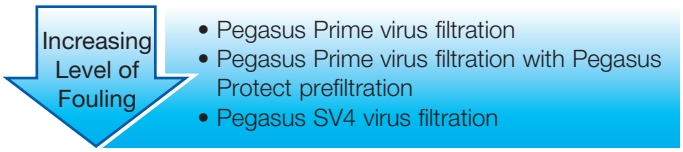
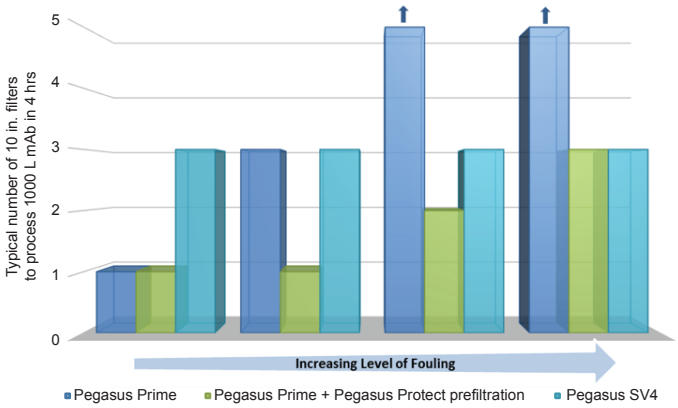


Figure 2

Relative Virus Filter Sizing in Fluids With Varying Fouling Characteristics



Specifications

Materials of Construction	Filter Cartridges	Kleenpak Nova Capsules
Filter Membrane	Polyethersulfone	Polyethersulfone
Support and Drainage	Polyester	Polyester
Endcap and adaptor	Polypropylene	Polypropylene
Core and cage	Polypropylene	Polypropylene
O-rings	Silicone elastomer	Silicone elastomer
Capsule hardware	--	Polypropylene
Valve seals	--	Silicone elastomer

Retention Ratings		
Pore size	20 nm (nominal)	
Virus	>4 log reduction value for mammalian parvoviruses	

Effective Filter Area (EFA) (Nominal)		
	1 m^2 (10.7 ft^2) per 10 in.	

Operating Parameters*		
Maximum Temperature	40 °C	40 °C
Maximum Pressure	–	5.4 bar (76 psi) at 20 ºC
		3.0 bar (43.5 psi) at 40 ºC
Maximum Differential Pressure	4.15 bar (60 psi)	4.15 bar (60 psi)

Recommended Operating Conditions		
	2.1 to 3.1 bard (30 to 45 psid)	
Sterilization	Supplied sterile (irradiated at > 25kGy)	
Shelf Life	1 year*	

** 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*

Aqueous Extractables (NVR)		
	Refer to Pall Publication USTR3143	

Dimensions (Nominal)	Filter Cartridges	Kleenpak Nova Capsules In-Line
Length	254 mm (10 in.) 508 mm (20 in.) 762 mm (30 in.)	335 mm (13.2 in.) 584 mm (23.0 in.) 834 mm (32.8 in.)
Diameter including valves	n/a	154 mm (6.1 in.)

Connection Type		
	n/a	1 in. sanitary flange inlet and outlet

Forward Flow Integrity Test		
	Water wet, diffusional flow integrity test	

Ordering Information

Part Number	Description	Filter Area	Pkg
AB1UPRM7PH4S	254 mm (10 in.) filter cartridge	1 m^2	1/pkg
AB2UPRM7PH4S	508 mm (20 in.) filter cartridge	2 m^2	1/pkg
AB3UPRM7PH4S	762 mm (30 in.) filter cartridge	3 m^2	1/pkg
NP1LUPRMP1S	25 mm (1 in.) Kleenpak Nova capsule (In-line style)	0.1 m^2	1/pkg
NP5LUPRMP1S	127 mm (5 in.) Kleenpak Nova capsule (In-line style)	0.5 m^2	1/pkg
NP6LUPRMP1S	254 mm (10 in.) Kleenpak Nova capsule (In-line style)	1 m^2	1/pkg
NP7LUPRMP1S	508 mm (20 in.) Kleenpak Nova capsule (In-line style)	2 m^2	1/pkg
NP8LUPRMP1S	762 mm (30 in.) Kleenpak Nova capsule (In-line style)	3 m^2	1/pkg
NT6UPRMP1S	254 mm (10 in.) Kleenpak Nova capsule (T-style)	1 m^2	1/pkg
NT7UPRMP1S	508 mm (20 in.) Kleenpak Nova capsule (T-style)	2 m^2	1/pkg
NT8UPRMP1S	762 mm (30 in.) Kleenpak Nova capsule (T-style)	3 m^2	1/pkg

Scaling Tools Part Number	Description	Filter Area	Pkg
3MCFPRM4	Microdisc capsules with Pegasus Prime filter membrane	2.8 cm^2	4/box
3MCFPRM12	Microdisc Capsules with Pegasus Prime filter membrane	2.8 cm^2	12/box
KA02PRM8FT	Mini Kleenpak™ capsule filterability tool***	204 cm^2	1/pkg

OPTIONAL - Pegasus Protect Prefilter			
4MCFPRT4	Microdisc capsules	3.8 cm^2	4/box
KA1PRT18FT	Kleenpak capsule filterability tool	286 cm^2	1/pkg
AB2PRT7PH4	508 mm (30 in.) filter cartridge†	1.4 m^2	1/pkg
NP7LPRTP1	Kleenpak Nova capsule (In-Line Style)†	1.4 m^2	1/pkg
NT7PRTP1	Kleenpak Nova capsule (T-Style)†	1.4 m^2	1/pkg

† Recommended for 254 mm (10 in.) Pegasus Prime Virus Filters to maintain a consistent prefiltration / virus filtration area from small scale trials. For larger virus filter sizes please contact Pall.

**** Filterability Tool version (FT). Not qualified for virus removal. For filterability tests only Consult individual product datasheets for technical specifications.*

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