

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



Process-Scale Virus Filtration

Pegasus Protect virus prefiltration combines with Pegasus Prime virus filtration to deliver the first gamma-sterilized pre-filter & virus filter combination. Together, these simplify process development, validation and operations while saving time and delivering improved process economy.

Process developers can quickly deliver a robust, scalable virus filtration process using a minimum of sample volume, and be confident of successful virus validation. This choice supports clinical manufacturing with a solution that is easy to use and versatile to work alone or with integrated and automated single-use systems.

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.

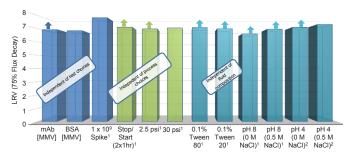
Features and Benefits

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

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.

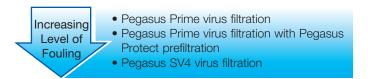
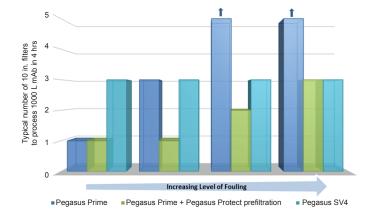


Figure 2Relative Virus Filter Sizing in Fluids With Varying Fouling Characteristics



² Tested using phage **\$\phi\$X174**

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		

HEU	ciiuoi	เ เเฉนแรง

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 °C	
		3.0 bar (43.5 psi) at 40 °C	
Maximum Differential Pressure	4.15 bar (60 psi)	4.15 bar (60 psi)	

Recommended Operating Conditions

	<u> </u>	
	2.1 to 3.1 bard (30 to 45 psid)	
Sterilization	Supplied sterile (irradiated at > 25kGy)	
Shelf Life	3 years	

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 Class Integrity Test			
Forward Flow Integrity Test			
	Water wet, diffusional flow integrity test		

Ordering Information

Oruering iniviniation			
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



Corporate Headquarters

Port Washington, NY, USA +1.800.717.7255 toll free (USA) +1.516.484.5400 phone

European Headquarters

Fribourg, Switzerland +41 (0)26 350 53 00 phone

Asia-Pacific Headquarters

Singapore +65 6389 6500 phone

Visit us on the Web at www.pall.com/biotech Contact us at www.pall.com/contact

International Offices

Pall Corporation has offices and plants throughout the world in: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, India, Indonesia, Ireland, Italy, Japan, Korea, Malaysia, New Zealand, Norway, Philippines, Poland, Russia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, United Kingdom, and Vietnam. Distributors in all major industrial areas of the world. To locate the Pall office or distributor nearest you, visit www.pall.com/contact.

The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

© 2020, Pall Corporation. Pall, (ALL), Kleenpak, and Pegasus are trademarks of Pall Corporation. ® indicates a trademark registered in the USA. TM indicates a common law trademark. Filtration.Separation. Solution. is a service mark of Pall Corporation.