

Pegasus™ Prime

VIRUS REMOVAL FILTER CARTIDGES AND CAPSULES

Process-scale virus filtration

Pegasus™ Prime virus filters combine with Pegasus Protect virus prefilters to deliver an innovative gamma-sterilized pre-filter and virus filter combination. Together, these can 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 low sample volume, supporting of successful virus validation. This choice supports clinical manufacturing with a solution that is easy to use and versatile enough 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 a high degree of manufacturing control, flexibility and security.

Features and benefits

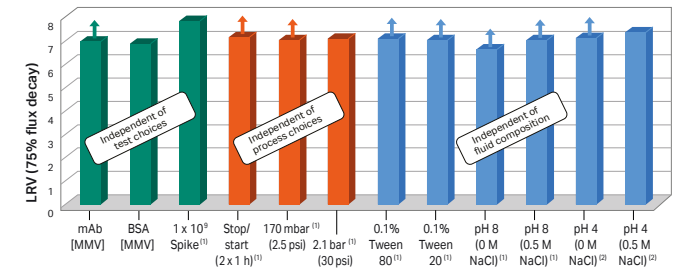
Features	Benefits
Robust high LRV, independent of process fluid or process parameters	Stable performance in a broad process design space <ul style="list-style-type: none">Optimize process flexibility to reduce the risk of process deviations
Robust capacity and high flow	Small filtration footprints and short process times <ul style="list-style-type: none">Economic processes and easy integration into automated processes
Gamma-irradiated, sterile and disposable	Ready to use <ul style="list-style-type: none">No need for additional sterilisation or sanitisation procedures
Full scale-up range	Predictable performance at all scales <ul style="list-style-type: none">Simple process development
Full pre-filter scale-up range with consistent pre-filter to virus-filter area ratios	Control scale-up risks <ul style="list-style-type: none">Faster, simplified scale-up
Water wet integrity testing	Easy to use <ul style="list-style-type: none">As simple to use as sterile filtration



Fig 1. 10 in. filter cartridge and Kleenpak™ Nova filter capsule.

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

The data illustrated in Figure 2 demonstrate the reliable and stable performance across a wide range of process conditions and highlights process flexibility that makes Pegasus Prime virus filtration an excellent first choice virus filter for bioprocesses.



⁽¹⁾ Tested using phage PP7
⁽²⁾ Tested using phage φX174

Fig 2. Robust, high virus retention.

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 3. These data illustrate that our comprehensive virus filtration portfolio can reduce the number of virus filters required for any given process. The most common economical solutions are shown below.

Increasing level of fouling

- Pegasus Prime virus filtration
- Pegasus Prime virus filtration with Pegasus Protect prefiltration
- Pegasus SV4 virus filtration

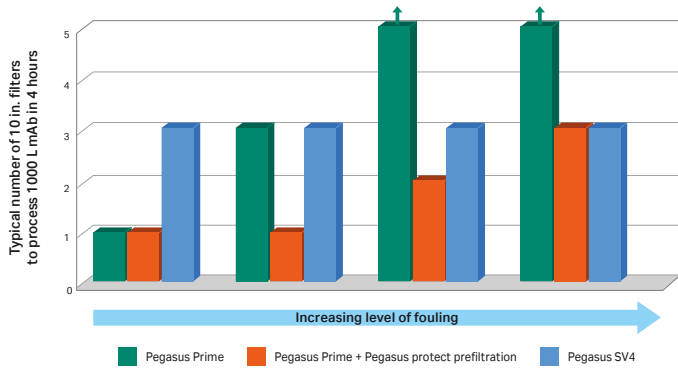


Fig 3. Relative virus filter sizing in fluids with varying fouling characteristics.

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°C 3.0 bar (43.5 psi) at 40°C
Maximum differential pressure		4.15 bar (60 psi)

Recommended operating conditions

2.1 to 3.1 bard (30 to 45 psid)

Sterilization

Supplied sterile (irradiated at > 25kgy)
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Shelf life

3 years

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

Aqueous extractables (NVR)

Refer to validation guide

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
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Forward flow integrity test

Water wet, diffusional flow integrity test
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Ordering information

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

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CY40883-05Dec23-DF

