Pegasus[™] Prime

VIRUS REMOVAL FILTERS

Pegasus™ Prime virus filters deliver an economic virus filtration solution with a small footprint, for easy integration into single-use and automated processes. With a combination of high log reduction value (LRV), high throughput, and high flow, they are suitable for monoclonal antibody (mAb) and recombinant protein solutions.

For feed streams with high levels of fouling protein aggregates, Pegasus Prime filters can be combined with Pegasus Protect prefilters for high parvovirus retention, capacity and flux.

Options are available for steam-in-place (SIP) or gammasterilized filters for integration into single use systems, to suit all facility types.

Features and benefits

- > 4 LRV for mammalian parvovirus
- Robust capacity and high flow for small filtration footprint and short processing times
- Stable performance in a broad process design space
- · Robust retention maintained during process interruptions
- Suitable for continuous processing at low flux and pressure
- Predictable performance at all scales for simple process development
- Easy to install, use and integrity test
- · Flexible options to suit all facilities

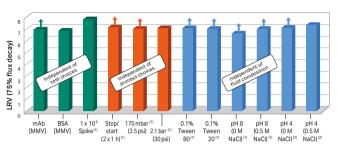


Fig 1. 254 mm (10 in.) filter cartridge and Kleenpak™ Nova filter capsule.



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

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



⁽¹⁾ Tested using phage PP7

Fig 2. Robust, high virus retention using Pegasus Prime virus removal filters (gamma sterile option).

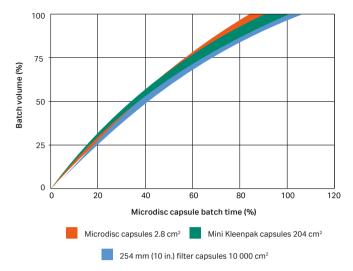
Scalability

The Microdisc capsules containing Pegasus Prime virus membrane are well suited for the confirmation and validation of performance at a small scale using minimal volumes of process fluid and virus spike preparations. They consistently deliver high LRV irrespective of the virus validation choices.

Microdisc capsules are available either gamma-sterilized or autoclavable, to support process development of SIP and pre-sterilized processes.

The performance confirmed during Microdisc capsule filterability trials shows how the filter scales reliably to full-scale devices (see Fig 3). Mini Kleenpak capsule filterability tools are available to help confirm performance during trials at intermediate scale. They contain the same Pegasus Prime virus prefilters in a low area, pleated filter configuration, to reduce the volume of fluid required.

Pegasus Protect prefilters also have a similar scale-up range with consistent pre-filter-to-virus filter area ratios for simplified process development and scaling.



Polyclonal immunoglobulin G (lgG) at 50% flux decay; $n \ge 9$ filters from three different lots.

Fig 3. Robust scaling.

⁽²⁾ Tested using phage ϕ X174

Materials of construction and dimensions

	Microdisc capsule	Mini Kleenpak capsule	AB style filter cartridge	Kleenpak Nova capsule
Materials of construc	ction			
Filter membrane	Polyethersulfone	Polyethersulfone	Polyethersulfone	Polyethersulfone
Support and drainage	Polyester	Polyester	Polyester	Polyester
Endcaps	Polypropylene	Polypropylene	Polypropylene	Polypropylene
O-rings	-	-	Silicone elastomer	Silicone elastomer
Connections	Female luer lock inlet, male slip luer lock outlet	13 mm (½ in.) sanitary flange inlet and outlet	Bayonet lock with fin end adaptor (code 7)	1 in. sanitary flange inlet and outlet
Dimensions				
Length (nominal)	21 mm	53 mm	254 mm (10 in.)	254 mm (10 in.)
			508 mm (20 in.)	508 mm (20 in.)
			762 mm (30 in.)	762 mm (30 in.)
Diameter	29 mm	73 mm	57 mm	 In-line style: 154 mm (including valves) T-style: 240 mm (including valves)
Filtration area	2.8 cm ²	204 cm ²	1 m²	1 m²
			2 m ²	2 m^2
			3 m^2	3 m ²

Operating parameters

	Microdisc capsule	Mini Kleenpak capsule	AB style filter cartridge	Kleenpak Nova capsule		
Maximum temperature	40°C	38°C	40°C	40°C		
Maximum operating differential pressure	• Gamma-sterile: 3.1 bar (45 psi)	3.1 bar (45 psi)	4.1 bar (60 psi)	4.1 bar (60 psi)		
	Autoclavable:4.1 bar (60 psi)					
Integrity test pressure	N/A	N/A	60 psi	60 psi		
Recommended operating conditions	2.1 to 3.1 bard (30 to 45 psid)	2.1 to 3.1 bard (30 to 45 psid)	2.1 to 3.1 bard (30 to 45 psid)	2.1 to 3.1 bard (30 to 45 psid)		
Sterilizing conditions	Gamma-sterile: pre-sterilized, installated at 200 kG.	Pre-sterilized, irradiated at > 25 kGy	Gamma-sterile: pre-sterilized, irradiated at > 25 kGy	Pre-sterilized, irradiated at > 25 kGy		
	irradiated at > 25 kGy		 SIP: non-sterile, autoclave or steam in situ, 125°C, 60 min, 1 cycle 			
	 Autoclavable: autoclave, 1 cycle submerged, 125°C, 60 min 					
Aqueous extractables (non-volatile residue [NVR])	Refer to validation guide					
Forward flow integrity test	Water wet, diffusional flow integrity test					

Ordering information

Microdisc capsule	Filter area	Sterilization	Package	Product code
Microdisc capsules with Pegasus Prime	2.8 cm ²	Gamma-sterile	4 per box	3MCFPRM4
virus removal filter membrane	2.8 cm ²	Gamma-sterile	12 per box	3MCFPRM12
	2.8 cm ²	Autoclavable	4 per box	3MCFSPRM4
	2.8 cm ²	Autoclavable	12 per box	3MCFSPRM12
Mini Kleenpak capsule				
Mini Kleenpak filterability tool with Pegasus Prime virus removal filter membrane	204 cm ²	Gamma-sterile	3 per box	KA02PRM8FT
AB style filter cartridge				
254 mm (10 in.) filter cartridge	1 m²	Gamma-sterile		AB1UPRM7PH4S
508 mm (20 in.) filter cartridge	2 m²	Gamma-sterile		AB2UPRM7PH4S
762 mm (30 in.) filter cartridge	3 m²	Gamma-sterile		AB3UPRM7PH4S
254 mm (10 in.) filter cartridge	1 m²	SIP or autoclavable		AB1SUPRM7PH4
508 mm (20 in.) filter cartridge	2 m²	SIP or autoclavable		AB2SUPRM7PH4
762 mm (30 in.) filter cartridge	3 m²	SIP or autoclavable		AB3SUPRM7PH4
Kleenpak Nova capsule				
25 mm (1 in.) Kleenpak Nova capsule (In-line style)	0.1 m²	Gamma-sterile		NP1LUPRMP1S
127 mm (5 in.) Kleenpak Nova capsule (In-line style)	0.5 m²	Gamma-sterile		NP5LUPRMP1S
254 mm (10 in.) Kleenpak Nova capsule (In-line style)	1.0 m²	Gamma-sterile		NP6LUPRMP1S
508 mm (20 in.) Kleenpak Nova capsule (In-line style)	2.0 m²	Gamma-sterile		NP7LUPRMP1S
762 mm (30 in.) Kleenpak Nova capsule (T-style)	3.0 m²	Gamma-sterile		NP8LUPRMP1S
254 mm (10 in.) Kleenpak Nova capsule (T-style)	1.0 m²	Gamma-sterile		NT6UPRMP1S
508 mm (20 in.) Kleenpak Nova capsule (T-style)	2.0 m²	Gamma-sterile		NT7UPRMP1S

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