Pegasus[™] Protect

VIRUS PREFILTER MEMBRANE WITH NOVASIP™ CAPSULES

Pilot-scale for small volume manufacture and scale-up confirmation

Pegasus[™] Protect virus prefiltration membrane is tailored to provide protection to Pegasus Prime virus filters and to deliver robust filter performance in more challenging process fluids. The combination of Pegasus Protect and Pegasus Prime filters increases throughput and can decrease processing costs by reducing virus filter sizing and processing times.

For small clinical batches, this product (CL2PRTP1) is our smallest available pharmaceutical-grade Pegasus Protect virus prefilter. It is to be used with our smallest pharmaceuticalgrade Pegasus Prime virus filter (NP1LUPRMP1S), maintaining a constant area ratio between prefilter and virus filter throughout all scales, from process development to small-scale and full-scale production.



Fig 1. Pegasus Protect membrane in Novasip[™] capsule (left) with Pegasus Prime virus filter capsule (right).

Features	Benefits
Removes filter plugging substances	Reduce plugging of Pegasus Prime virus filters: • Smaller virus filter sizing • Lower cost of goods • Shorter processing times • Can deal with natural process fluid variation
The scale-up range provides a consistent prefilter to virus filter area ratio at all scales	Consistent performance: • Controlling scaling risks • Faster, simplified scale-up
Disposable capsule with 1 in. sanitary outlet	Easy to use: • Direct connection to Kleenpak™ Nova NP1 capsule containing Pegasus Prime virus removal media



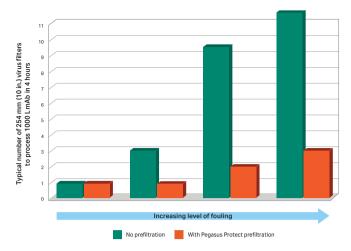


Fig 2. Impact of Pegasus Protect prefiltration on required virus filters per batch.

Scalable solutions

Prefiltration area and flowrate are critical variables that may affect the performance of Pegasus Protect prefiltration and Pegasus Prime virus removal filters when used in combination.

To control these variables, Pegasus Protect prefiltration media is available in a range of formats, designed to maintain a consistent prefilter to virus-filter ratio. This control enables predictable and consistent performance at all scales from the initial Microdisc capsule scale trials to clinical manufacturing.

	Area	Microdisc capsules	Area	CL2PRTP1 / 1 in. Kleenpak Nova capsule
Pegasus Protect prefiltration	3.9 cm ²		0.14 m ²	
Pegasus Prime virus filter	2.8 cm ²		0.1 m ²	
Area ratio	1.4:1		1.4 : 1	

Specifications

Materials of construction

Filter membrane: nylon Support and drainage: polyester Core and cage: polypropylene

Capsule bowl: polyetherimide

Capsule head: polyetherimide with TiO, whitener (1)

 $^{(1)}$ TiO₂ is an insoluble inorganic mineral filler that does not contribute to organic extractables

Retention ratings

Pore size 0.2 µm nominal

Effective filter area (EFA) (nominal)

0.14 m²

Operating parameters

Maximum temperature: 40°C Maximum pressure: 6.5 bar (94 psi) Maximum differential pressure: 5.4 bar (80 psi)

Recommended operating conditions

90 mbard (1.3 psid) or 0.8 L/min water at 20° C ⁽²⁾ ⁽²⁾ ⁽²⁾ When used with Pegasus Prime 25.4 mm (1 in.) Kleenpak capsules at 2.1 bar (30 psid)

Steam autoclaving

Cumulative autoclave time:

16 hours at 125°C ⁽³⁾

4 hours at 140°C

⁽³⁾ Laboratory tests (1-hour cycles). Contact us for recommended procedures WARNING: Gamma pre-sterilized capsules should not be steam autoclaved. They have not been validated for steam autoclaving

Dimensions (nominal)

Length: 15.7 cm (6.2 in.) Diameter including valves: 12.3 cm (4.8 in.)

Connection type

1 in. sanitary inlet/outlet

Ordering information

Product	Product code
Novasip filter capsules with Pegasus Protect prefiltration membrane. Nominal area 0.14 m ²	CL2PRTP1G
Novasip filter capsules with Pegasus Protect prefiltration membrane. Nominal area 0.14 m ² , gamma sterilized	CL2PRTP1S

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