

Pegasus™ Prime

VIRUS REMOVAL FILTER MEMBRANES IN MICRODISC CAPSULES

Small virus removal for bioprocesses

Pegasus™ Protect virus prefiltration combines with Pegasus Prime virus filtration to deliver one of the first gamma-sterilized pre-filter and virus filter combinations. Together, they 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 achieve their virus validation successfully. 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 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, and deliver consistently high log reduction value (LRV) irrespective of the virus validation choices.

The predicted process flow, filter capacity or virus retention established during these studies scales to a range of products available to support your process at all scales and offer an excellent degree of manufacturing control, flexibility and security.

Table 1. Features and benefits

Features	Benefits
Robust high LRV, independent of process fluid, process parameters or validation procedure	Reliable performance Reduced risk of validation variation or failures ensures rapid process
Robust capacity and high flow	Small filtration footprints and short process times Economic processes and easy integration into automated processes
Gamma-irradiated and fully disposable	Ready-to-use No need for additional sterilization or sanitization procedures
Full scale-up range with identical membrane at all scales	Reliable scalability Meaningful process prediction with minimal fluid volumes
Full pre-filter scale-up range with consistent pre-filter to virus filter area ratios	Control scale-up risks Faster, simplified scale-up
Easy to use	Luer lock connectivity for easy testing



Fig 1. Microdisc capsules with Pegasus Prime virus removal filter membrane.

Pegasus prime virus filter delivers robust, high LRV independent of process parameters, process fluid and validation choices.

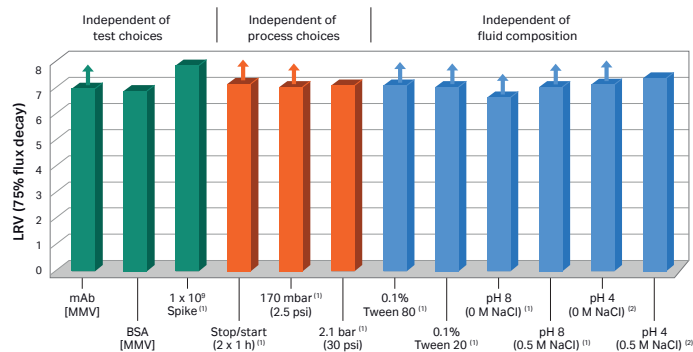


Fig 2. Robust, high virus retention.

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

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

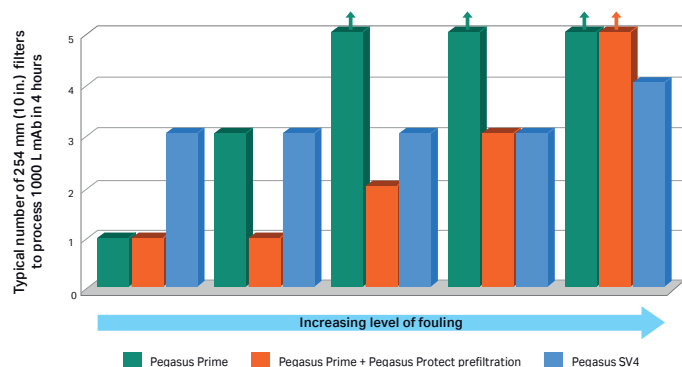
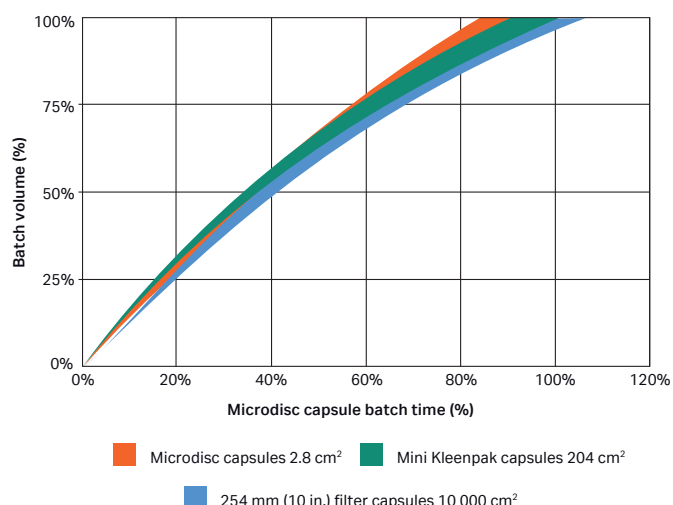


Fig 3. Robust virus filter sizing.

The performance established during Microdisc filterability trials scales reliably to full-scale devices as shown in Figure 4. Where intermediate scale trials to confirm the performance are required, Mini Kleenpak™ capsule filterability tools are available and contain the same Pegasus Prime virus prefilters in a low area, pleated filter configuration to reduce the volume of fluid required.



Polyclonal IgG at 50% flux decay; n ≥ 9 filters from three different lots.

Fig 4. Robust scaling.

Technical specifications

Materials of construction

Filter membrane: polyethersulfone

Capsule hardware: polypropylene

Support substrate: polyester

Retention ratings

Pore size: 20 nm nominal

Virus: > 4-log reduction value with mammalian parvoviruses

Effective filtration area (EFA) (nominal)

2.8 cm² (0.43 in.²)

Operating parameters

Maximum temperature: 40°C

Maximum pressure: 3.1 bar (45 psi, 0.31 MPa) ⁽³⁾

Maximum differential pressure: 3.1 bar (45 psi, 0.31 MPa) ⁽³⁾

⁽³⁾ Up to 12 h at 25°C; up to 6 h at 40°C

Sterilization

Gamma >25 kGy

Shelf life

3 (three) years

Liquid flow vs. differential pressure (typical)

1.4 to 2.6 mL/min at 2.1 bar (30 psid, 0.21 MPa), water at 20°C

Dimensions (nominal)

Length: 21 mm (0.8 in.)

Diameter: 29 mm (1.2 in.)

Connection type

Female luer lock inlet, male slip luer lock outlet

Ordering information

Description	Package	Product code
Microdisc capsules with	4 per box	3MCFPRM4
Pegasus Prime virus	12 per box (4 × 3)	3MCFPRM12
removal filter membrane		

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