



Biotech

USD3141a

Pall Microdisc Capsules with Pegasus™ Prime Virus Removal Filter Membrane



Small Virus Removal for Bioprocesses

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 Microdisc capsules containing Pegasus Prime virus media are ideal 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 the highest degree of manufacturing control, flexibility and security.

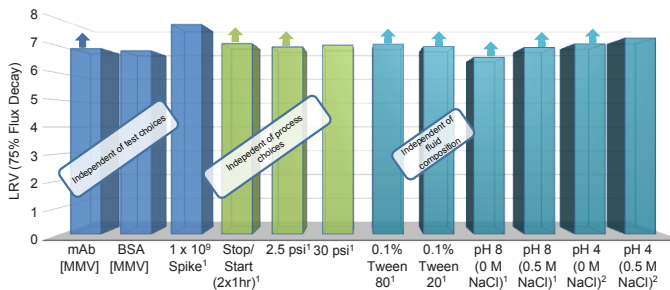
Filtration. Separation. Solution.SM

Features and Benefits

Robust high LRV, independent of process fluid, process parameters or validation procedure	Reliable performance and assured patient safety <ul style="list-style-type: none"> Minimized risk of validation variation or failures ensures rapid process development
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 and fully disposable	Ready-to-use <ul style="list-style-type: none"> No need for additional sterilisation or sanitisation procedures
Full scale-up range with identical membrane at all scales	Reliable scalability <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Faster, simplified scale-up
Easy to use	Luer Lock connectivity for easy testing

Pegasus Prime delivers robust, high LRV independent of process parameters, process fluid and validation choices.

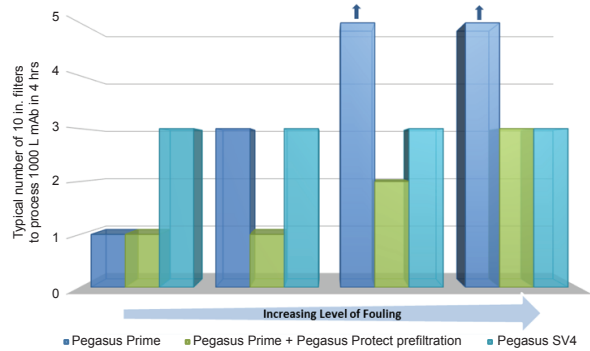
Figure 1
Robust, High Virus Retention



¹Tested using phage PP7
²Tested using phage ϕ X174

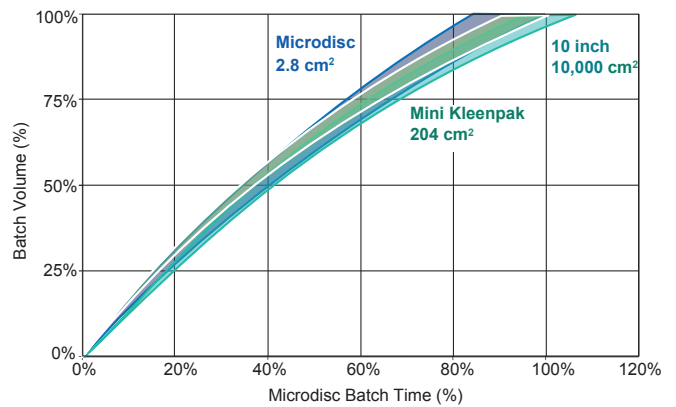
Pegasus Prime combines high LRV with high throughput and high flow in all mAb solutions to deliver an economic virus filtration solution with a small footprint for easy integration into single-use and automated processes.

Figure 2
Robust Virus Filter Sizing



The performance established during Microdisc filterability trials scales reliably to full scale devices as shown in Figure 3. Where intermediate scale trials to confirm the performance are required, Mini Kleenpak filterability tools are available and contain the same Pegasus Prime virus media in a low area, pleated filter configuration to minimize the volume of fluid required.

Figure 3
Robust Scaling



• Polyclonal IgG at 50% flux decay; n \geq 9 from 3 different lots

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 Filter Area (EFA) (Nominal)

2.8 cm² (0.43 in.²)

Operating Parameters

Maximum Temperature: 40 °C
Maximum Pressure: 3.1 bar (45 psi)*
Maximum Differential Pressure: 3.1 bar (45 psi)*
**up to 12 hours at 25 °C; up to 6 hours at 40 °C*

Sterilization

Gamma >25 kGy

Shelf Life

1 year

Liquid Flow v Differential Pressure (Typical)

1.4 – 2.6 mL/min at 2.1 bar, 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 outlet

Ordering Information

Part Number	Description	Pkg
3MCFPRM4	Pall Microdisc Capsules with Pegasus Prime Virus Removal Filter Membrane	4/box
3MCFPRM12	Pall Microdisc Capsules with Pegasus Prime Virus Removal Filter Membrane	12/box (4 x 3 lots)



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