

Pegasus™ Prime

VIRUS REMOVAL MEMBRANE IN MINI KLEENPAK™ CAPSULE FORMAT

Simple tools for scale-up confirmation

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 process economy.

Process developers can quickly deliver a robust, scalable virus filtration process using a low 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 Mini Kleenpak™ capsules containing Pegasus Prime virus filter membrane are optimized as a filterability tool suitable for the confirmation of performance during pre-clinical process development.

As shown in Figure 2, the filter sizing and process times confirmed during these studies can scale to a range of products available to support your process during clinical manufacture. Where required, they can then be integrated into single-use and automated solutions to offer a high degree of control, flexibility and security.

Features and benefits

Features	Benefits
Part of a full scale-up range with identical membrane at all scales ⁽¹⁾	Reliable scalability: meaningful process prediction to reduce oversizing of large-scale virus filtration
Gamma-irradiated	Ready to use: no need for additional sterilization or sanitization procedures
Connectivity with sanitary connection	Easy to use: easy connection to pre filtration capsules
Small fill volume	Economic process confirmation

⁽¹⁾ Mini Kleenpak capsule filterability tools are for filter-sizing studies and evaluation during process development only. They are not qualified for virus removal. Cytiva provides filters for use during drug manufacture or for animal, human therapeutic or diagnostic needs. Please contact us for details of these filters where needed as Mini Kleenpak capsule filterability tools are not intended for these purposes.



Fig 1. Mini Kleenpak with Pegasus Prime virus removal filter membrane.

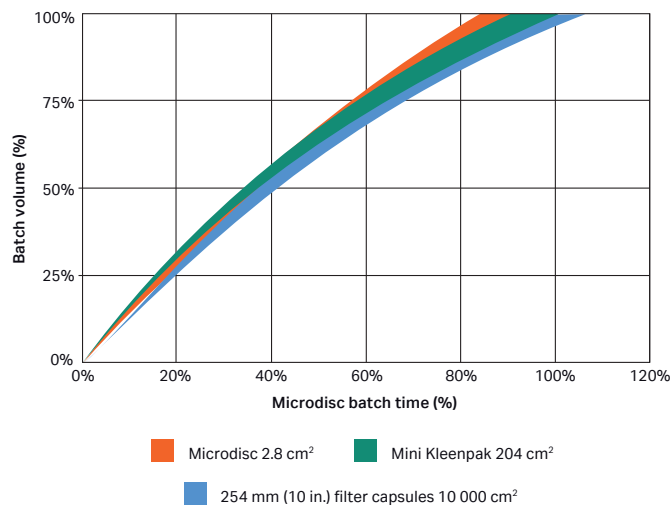


Fig 2. Robust scaling: Polyclonal IgG at 50% flux decay; n≥9 from three different lots.

Technical specifications

Materials of construction

Filter membrane: polyethersulfone (PES)

Support and drainage: polyester

Capsule shell, core and endcaps: polypropylene (PP)

Retention ratings ⁽²⁾

Pore size: 20 nm nominal

Virus: > 4-log reduction value with mammalian parvoviruses

Effective filtration area (EFA) (nominal)

204 cm² (31.6 in.²)

Operating parameters ⁽²⁾

Maximum temperature: 38°C

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

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

⁽²⁾ In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction

⁽³⁾ Up to 12 h at 25°C; up to 6 h at 38°C

Sterilization

Gamma >25 kGy

Liquid flow vs. differential pressure (typical)

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

Dimensions (nominal)

Maximum diameter including valves: 53 mm (2.1 in.)

Length: 73 mm (2.9 in.)

Connection type

13 mm (½ in.) sanitary flange inlet and outlet

Ordering information

Description	Pkg	Product code
Mini Kleenpak filterability tool with Pegasus Prime virus removal filter membrane. Supplied gamma-irradiated.	3/pkg	KA02PRM8FT

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