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Product Guide

Viresolve® Pro Solution
Prefilter Selection Guide

Membrane filtration is a critical virus reduction step in most established and new biologic production processes. However, even for highly purified process intermediates, protein aggregates and other impurities can limit the throughput capacity of virus filters, increasing filter area requirements. To mitigate these challenges, many filtration operations include prefilters to improve the capacity of virus filters, consistency of process runs, and enhance process economics.

Prefilter selection is driven by the characteristics of the feed stream and different processing needs. In general, adsorptive or charge-based binding is more effective than retention based on size-exclusion for removing plugging aggregates from monoclonal antibody (mAb) process streams. Our prefilter portfolio works with feed streams encompassing a broad range of pH and conductivities and a range of manufacturing configurations. This guide provides an overview of key criteria to consider when selecting a prefilter to improve Viresolve® Pro Device capacity.

Viresolve® Pro Shield*

- Surface-modified membrane filter
- Cation exchange adsorptive chemistry
- Caustic stable
- Low extractables

Viresolve® Pro Shield H*

- Surface-modified membrane filter
- Mixed mode adsorptive chemistry
- Caustic stable
- Low extractables

Viresolve® Prefilter

- Adsorptive depth filter
- Mixed mode/hydrophobic adsorptive chemistry
- Autoclavable
- Extractables assessment may be needed

Millistak+® HC Pro X0SP*

- Adsorptive depth filter
- Mixed mode adsorptive chemistry
- Low extractables

* Supported by the Emprove® Program.

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Capacity Improvements

The capacity of the Viresolve® Pro Device with adsorptive depth or surface modified membrane prefilters was evaluated with a human IgG (4 g/L) feed stream under different pH and conductivity conditions. Figure 1 shows the benefits of different prefilters on the capacity of the Viresolve® Pro Device at 75% flow decay (V75). In general, all prefilters enhanced the capacity of the virus filter, however the extent of capacity increase was highly dependent on both the prefilter and the pH and conductivity of the feed stream.

Feed Conditions

The performance of each prefilter is defined by feed characteristics: the Viresolve® Prefilter and Millistak+® HC Pro X0SP depth filters have broad operating windows and provide optimal capacity improvements when the pH of the process fluid is greater than pH 6 or conductivity is at least 4 mS/cm.

The operating windows of the Viresolve® Pro Shield and Shield H prefilters are shown in Figure 2. Although this contour plot highlights where the prefilters will work best, favorable performance is also observed at the margins of these windows.

Extractables

All of our prefilters have low levels of extractables. However, the Viresolve® Prefilter contains cellulose, a material with potential to contribute quantifiable, but non-toxic, levels of beta glucans and metals. Although such trace extractables are typically removed after virus filtration during ultrafiltration and diafiltration, some users perform a risk assessment to determine their potential impact. For further guidance, refer to our application note titled Viresolve® Prefilter: Extractables Characterization (TB4111EN00).

Hardware – For Process Scale filters only

Viresolve® Pro Shield and Shield H can be co-implemented with the Viresolve® Pro Device in the same holder.

Viresolve® Prefilter and Millistak+® HC Pro X0SP depth filter require a dedicated holder and should not be stacked in the same holder as the Viresolve® Pro Device.

Scaling and Screening Tools

Each prefilter is offered in a small-scale format for process development and viral clearance studies.

- Viresolve® Pro Shield and Viresolve® Pro Shield H Micro devices have a filtration area of 3.1 cm^2.
- Viresolve® Prefilter Optiscale® 40 devices have a filtration area of 5 cm^2.
- Millistak+® HC Pro X0SP depth filters are available in a NanoPod (NP6) format with 6 cm^2 filtration area requiring minimal feed stream volumes or a 20 cm^2 Micro 20 format.

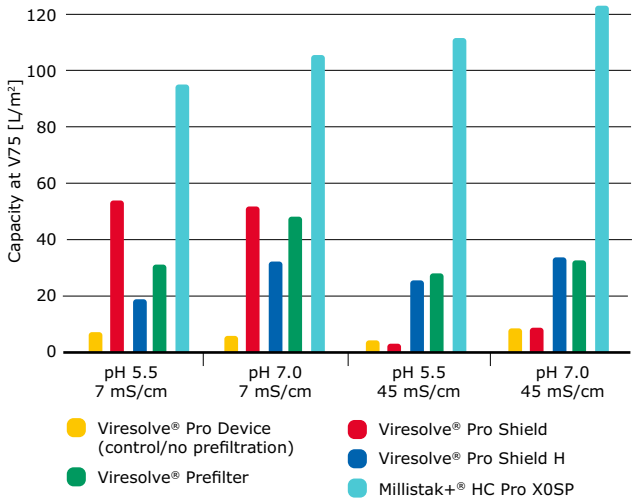

Figure 1.

Viresolve® Pro Device capacity at 75% flow decay with different prefilters directly upstream of the virus filter.

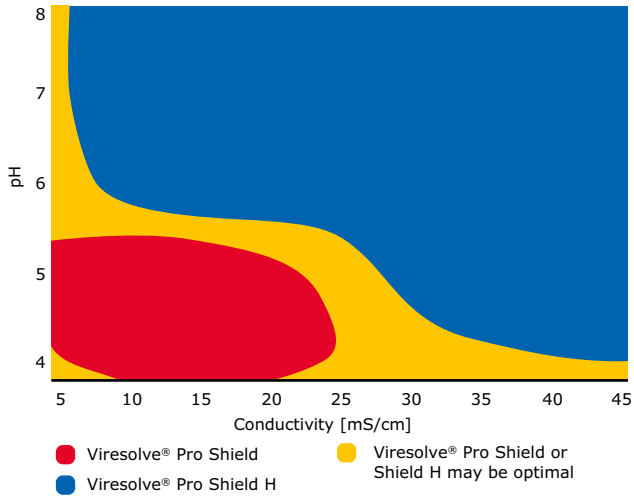

Figure 2.

Contour plot showing pH and conductivity conditions for optimal performance of Viresolve® Pro Shield or Shield H.




Quick Selector

	Viresolve® Pro Shield	Viresolve® Pro Shield H	Viresolve® Prefilter	Millistak+® HC Pro X0SP
Binding media	Surface modified polyethersulfone (PES) membrane	Surface modified polyethersulfone (PES) membrane	Adsorptive depth filter containing diatomaceous earth and mixed esters of cellulose	Adsorptive depth filter containing silica filter aid with polyacrylic fiber
Optimum pH and conductivity	pH ≤6 **AND** cond. ≤30 mS/cm	pH ≥5.5 **OR** cond. ≥25 mS/cm	pH ≥4 **AND** cond. ≥4 mS/cm	pH ≥4 **AND** cond. ≥4 mS/cm
Extractables	Low extractables	Low extractables	Risk assessment may be desired (contains cellulose)	Low extractables
Hardware – For Process Scale only	Co-implement with Viresolve® Pro Device in same holder	Co-implement with Viresolve® Pro Device in same holder	Requires standalone holder	Requires standalone holder

Virus filtration process development and optimization studies are recommended for difficult-to-filter feed streams.
For more information on process development services, please contact your local representative.

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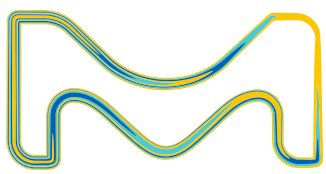

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