Virosart® HF

High speed virus filtration for mAbs and recombinant proteins

Product Information

Virosart® HF combines highest virus safety with excellent capacities. This high speed virus filter is especially designed for easy implementation into single-use processes. The smart capsule design with low footprint and minimal flushing volumes can easily be implemented into pre-sterilized ready to use assemblies.

Description

Choose your perfect fit from the Sartorius virus clearance strategy summarizing orthogonal technologies, manufacturing solutions, validation support and consultancy. The orthogonal technologies from Sartorius consisting of virus adsorption by chromatography, virus inactivation and virus filtration. The Virosart® product range includes four different virus retentive membranes, in order to provide the best solution for every application. Virosart® HF targets the removal of both small non-enveloped viruses (20 nm) e.g. PPV, MVM and larger enveloped viruses (> 50 nm) e.g. MuLV from biopharmaceutical feed streams.

Application & Positioning

The main applications for Virosart® HF for virus retentive filtration are monoclonal antibodies (Mab), antibody fragments (Fab) or small recombinant proteins (< 150 kD). Virosart® HF is used at the end of the purification process for virus filtration of the biopharmaceutical product. At this stage the purity of the biopharmaceutical product is the highest and virus filter blockage due to contaminants (DNA, CHOP, aggregates & lipoproteins) is the lowest. Even if these contaminants should be removed during the polishing process of the target molecule, small amounts might be sufficient to cause premature blockage of the final virus filter. To prevent this, an efficient pre-filtration step, such as the Virosart® Max*, might be required as protection for the Virosart® HF membrane.

Product Benefits

Virosart® HF provides high virus safety to the biopharmaceutical product. Based on a unique modified PES membrane, Virosart® HF provides highest flow rates and excellent capacity. The high packing density of the elements combines extremely low hold up and flushing volumes with low footprint requirements.

The sterile delivery secures ease of use as well as fast installation of the filter elements. Virosart® HF retains ≥ 4 LRV of small non-enveloped viruses (e.g. PPV, MVM) and ≥ 6 LRV of large enveloped viruses (e.g. MuLV). This filter offers high virus safety over the entire flow decay profile independently of operating pressure.

Integrity Testing

Virosart® HF are tested for integrity using a water-based diffusion test, e.g. based on the Sartocheck® technology of Sartorius Stedim Biotech. Virosart® HF filters have been validated for 4 LRV removal of small non-enveloped viruses (e.g. PPV, MVM) and ≥ 6 LRV of large enveloped viruses (e.g. MuLV). This filter offers high virus safety over the entire flow decay profile independently of operating pressure.

* Virosart® Max is a specifically optimized virus pre-filter significantly increasing downstream virus filter performance. Virosart® Max is a patented technology (DE 10 2011 105 525 B4) binding aggregates efficiently through hydrophobic interactions with polyamide, independently of process conditions such as conductivity from biological feed streams (mAbs, plasma derivatives or recombinant proteins).
### Nominal filtration area

<table>
<thead>
<tr>
<th>Module</th>
<th>Lab Module</th>
<th>Mid-Scale Module</th>
<th>Process Module</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.7 cm² ± 5.0 cm²</td>
<td>200 cm² ± 0.2 m²</td>
<td>0.8 m² ± 2.4 m²</td>
</tr>
<tr>
<td></td>
<td>0.22 ft² ± 2.15 ft²</td>
<td>8.6 ft² ± 25.8 ft²</td>
<td></td>
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</tbody>
</table>

### To be used for

- Scale-down work
- Flow & capacity studies
- Optimization of pre-filter- | final-filter-ratio
- GLP spiking studies
  (IT tested version)
- Scale-up studies
- Small scale production
- Large scale manufacturing

### Typical filtration volume

- < 500 mL
- < 50 L
- > 50 L

### Delivery status

- Sterile (γ-irradiated)
- Non-sterile (γ-irradiated in single-use assembly)
- Sterile (γ-irradiated)
- Non-sterile (γ-irradiated in single-use assembly)

### Available connectors

- Inlet, outlet & vent: Luer lock
- Inlet & vent: ¾" sanitary connector
- Outlet: Hose barb
- Inlet & vent: 1½" sanitary connector
- Outlet: ¾" sanitary connector

### Operating parameters

- In the direction of filtration: max. 5.0 bar | 73 psi at 20°C
- In the reversed direction of filtration: max. 2.5 bar | 36.3 psi at 20°C
### Materials

<table>
<thead>
<tr>
<th>Process &amp; Mid-Scale Module</th>
<th>Lab Module</th>
<th>Membrane</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resin Polyurethane</td>
<td>Resin Polyurethane</td>
<td>Material Polyetersulfone</td>
</tr>
<tr>
<td>Housing Polypropylene</td>
<td>Housing Polycarbonate</td>
<td>Pore size 20 nm nominal</td>
</tr>
<tr>
<td>Protective sleeving Polyamid</td>
<td>Protective sleeving Non</td>
<td>Format Hollow fiber</td>
</tr>
<tr>
<td>End caps Polypropylene</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

![Diagram of module with labels](image)

- **300 μm**
- **Inlet**
- **Outlet**
- **Venting**
Performance

Characteristic Water Flow Rates

Virosart® HF Process module (2.4 m² | 25.8 ft²)

Virosart® HF Mid-Scale Module (0.2 m² | 2.15 ft²)

Virosart® HF Lab Module (5.0 cm²)

Virosart® HF Process module (0.8 m² | 8.6 ft²)

Virosart® HF Mid-Scale Module (200 cm² | 0.22 ft²)

Virosart® HF Lab Module (1.7 cm²)
Regulatory Compliance

- Each individual filter is tested for integrity (except 3VI--28-TCGML--V & 3VI--28-BCGML--V) and for water flux during manufacturing.
- Validated for ≥ 4 LRV removal of small non-enveloped viruses using bacteriophage PP7.
- Designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System.
- Meet or exceed the requirements for WFI quality standards set by the current USP.
- Non pyrogenic according to USP Bacterial Endotoxins.

Technical References

- Validation Guide: SPK5801-e
- Extractables Guide: SPK5804-e
- Virus Information Guide: SPK5752-e
- Publication: Virus Filtration Using a High Throughput Parvovirus Retentive Membrane; Roederstein/Thom, BioPharm International, Aug 2013
- Application Note: Impact of Pressure Release and Multiple Pressure Fluctuations on Virus Retention Performance, SPK4112-e
- Risk Mitigation for Calcium Chloride Solution, SPK4114-e

Ordering Information

Process Module

- Filtration area
  - M: 2.4 m² | 25.8 ft²
  - H: 0.8 m² | 8.6 ft²
- Sterilization
  - G: γ-irradiated

Mid-Scale Module

- Filtration area
  - F: 0.2 m² | 2.15 ft²
  - D: 200 cm² | 0.22 ft²
- Sterilization
  - G: γ-irradiated

Lab Module

- Filtration area
  - B: 5.0 cm²
  - T: 1.7 cm²
- Sterilization
  - G: γ-irradiated
- IT: Integrity tested
- IT: Not integrity tested
- Units per package
  - V: Two pieces
Accessories & Services

Adaptive Pre-Filtration
Virosart® Max protects your virus filter irrespective of the process conditions. Virosart® Max will downsize your process and reduce your total virus filtration costs*.

Integrity Testing
Fully automated Virosart® integrity testing to guarantee intactness of the Virosart® filter pre- and post diffusion test.

Ready-to use Filter Transfer Sets
Simplify your daily routine work by using modular filter assembly.

Single-use Systems
Flexible processing with FlexAct® VR system for production from pilot plants up to commercial processing.

Customized Systems
High level of automation and individual requirements can be relegalized by customized single-use or hybrid solutions.

Testing Service
Your partner to assure virus safety for your process by MCB | WCB characterization, bulk harvest testing and spiking studies.

Services Worldwide
Trust our comprehensive range of services for your virus filtration processes: We gladly assist you with tasks like process validation, process optimization and many more.