SARTORIUS

Product Datasheet

Virosart® HF

High-Speed Virus Filtration for MAbs and Recombinant Proteins

Product Information

Virosart® HF combines exceptional virus retention 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 be easily implemented into pre-sterilized, ready-to-use assemblies.

Choose your perfect fit from the Sartorius virus clearance strategy summarizing orthogonal technologies, manufacturing solutions, validation support and consultancy. The orthogonal technologies from Sartorius consist of virus inactivation as well as virus removal by chromatography and virus filtration.

The Virosart® product range comprises four different virus retentive membranes to find 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.

Introduction

Application & Positioning
The main applications for Virosart® HF for virus retentive filtration are monoclonal antibodies (mAb), antibody fragments (Fab) and small recombinant proteins (< 150 kDa). 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 the probability of virus filter blockage due to contaminants (DNA, CHOP, aggregates and lipoproteins) is the lowest.

Although 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 efficient virus removal for the biopharmaceutical product. Based on a uniquely 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 $\log_{10}$ of small non-enveloped viruses (e.g. PPV, MVM) and ≥ 6 $\log_{10}$ of large enveloped viruses (e.g. MuLV). This filter offers excellent virus retention over the entire flow decay profile independently of operating pressure.

Customized process-specific virus LRV determination can be individually provided by our Confidence® Virus Clearance Services (see page 7 for details).

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 logarithmic reduction values of ≥ 4 $\log_{10}$ for small non-enveloped viruses using bacteriophage PP7 as the model virus. Validation data

* 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 (plasma derivatives or recombinant proteins).

Technical Data

	Lab Module	Mid-Scale Module	Process Module
Nominal filtration area	1.7 cm² & 5.0 cm²	200 cm² & 0.2 m² 0.22 ft² & 2.15 ft²	0.8 m² & 2.4 m² 8.6 ft² & 25.8 ft²
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)	▪ Sterile (γ-irradiated) ▪ Non-sterile (γ-irradiatable)	▪ Sterile (γ-irradiated) ▪ Non-sterile (γ-irradiatable)
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		

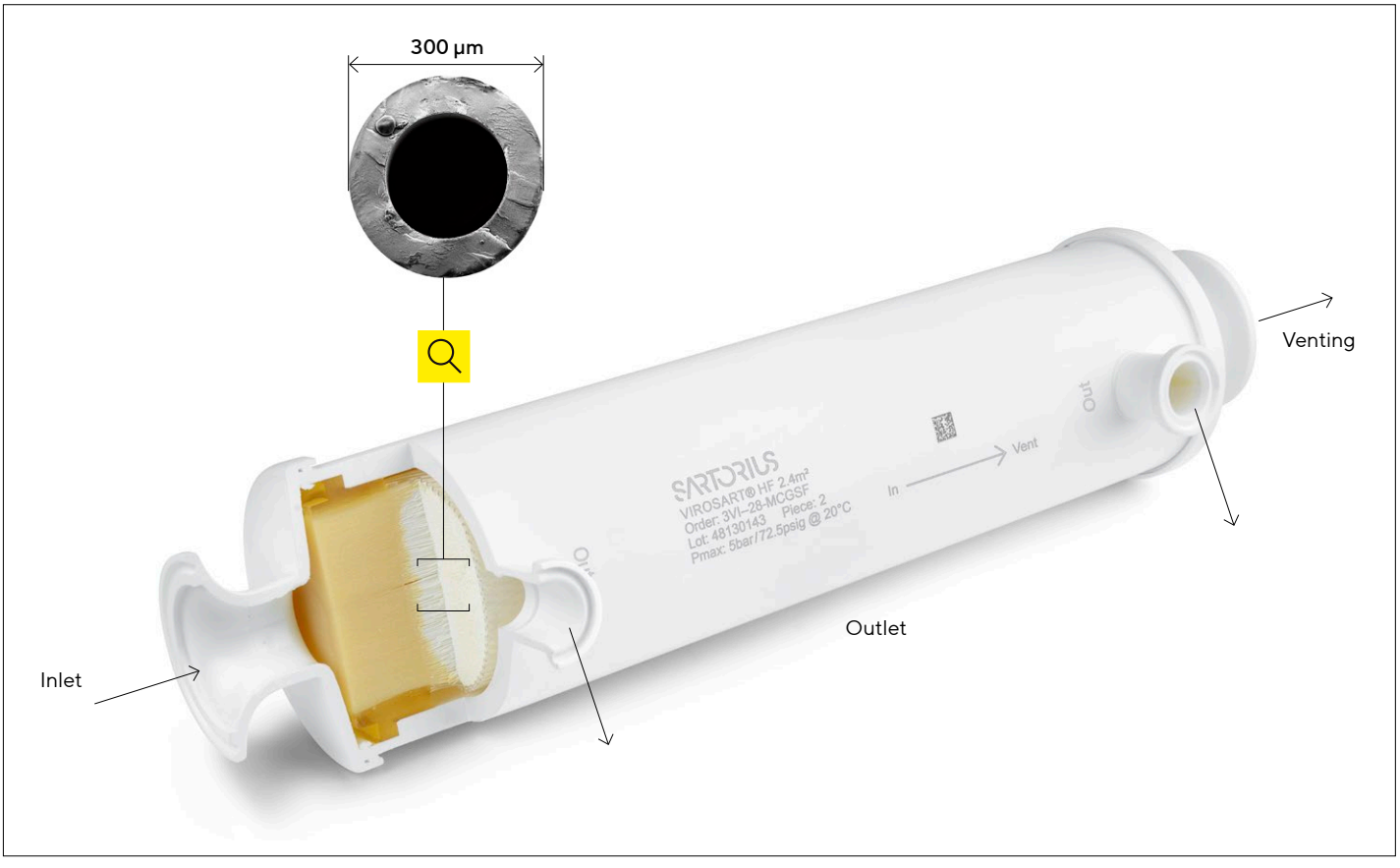
Note. Mid-scale and process-scale modules are additionally also available as virus filter transfer units. They are delivered pre-assembled and sterile (γ-irradiated). Learn more about Virus Filter Transfer Units in the in the datasheet.

Materials

Process & Mid-Scale Module	
Resin	Polyurethane
Housing	Polypropylene
Protective sleeving	Polyamide
End caps	Polypropylene

Lab Module	
Resin	Polyurethane
Housing	Polycarbonate
Protective sleeving	Non

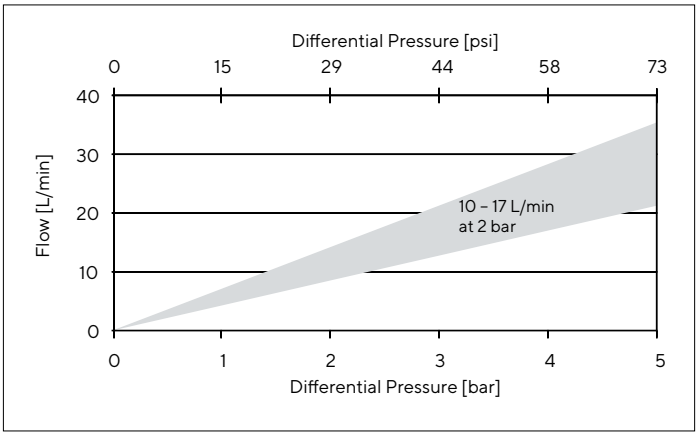
Membrane	
Material	Polyethersulfone
Pore size	20 nm nominal
Format	Hollow fiber



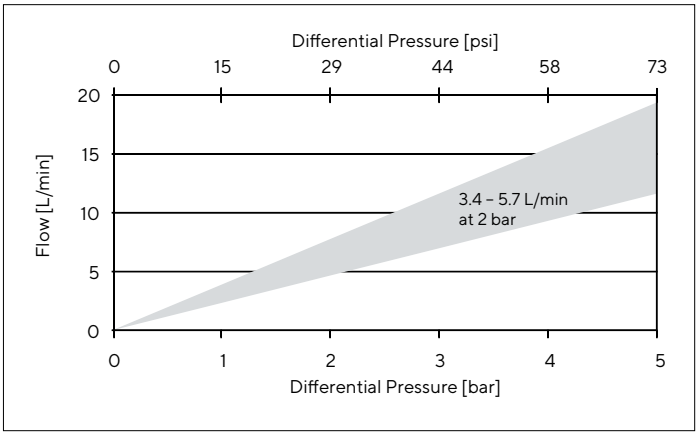
Performance

Characteristic Water Flow Rates

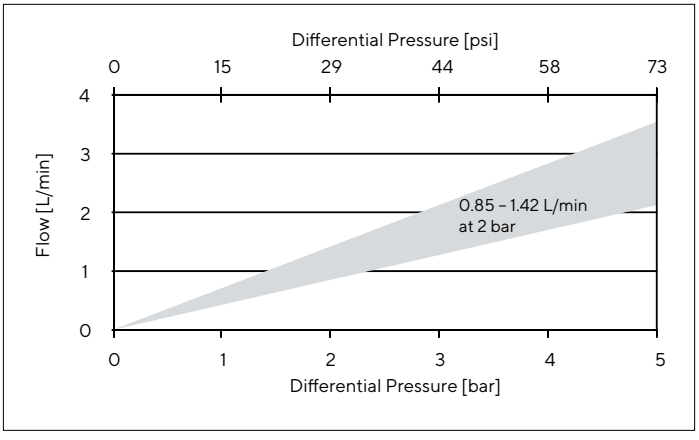
Virosart® HF Process Module (2.4 m² | 25.8 ft²)



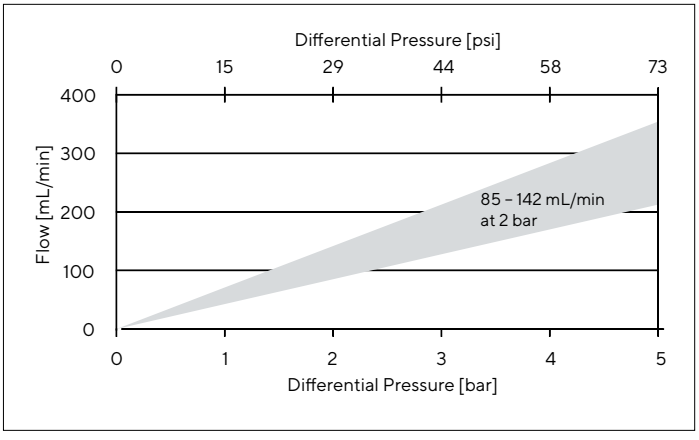
Virosart® HF Process Module (0.8 m² | 8.6 ft²)



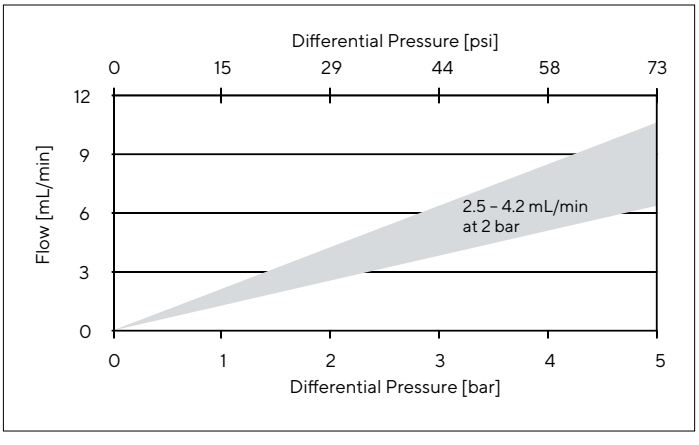
Virosart® HF Mid-Scale Module (0.2 m² | 2.15 ft²)



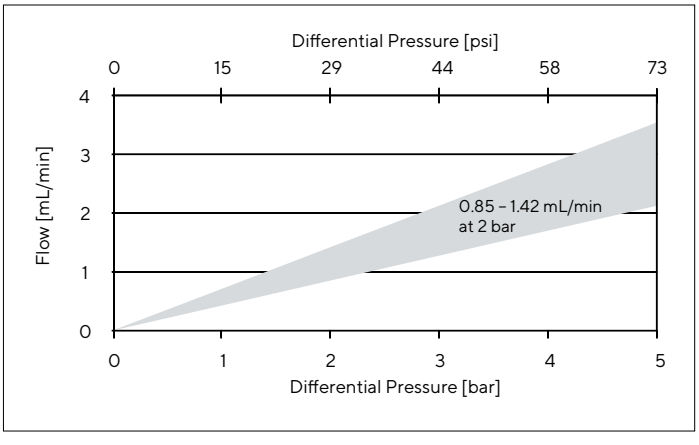
Virosart® HF Mid-Scale Module (200 cm² | 0.22 ft²)



Virosart® HF Lab Module (5.0 cm²)



Virosart® HF Lab Module (1.7 cm²)



Redulatory 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 $\log_{10}$ 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

References

Technical References	Publication No.
Validation Guide	SPK5801-e
Extractables Guide	SPK5804-e
Virus Information Guide	SPK5752-e

Application Note	Publication No.
Autoclaving Virosart® Minisart® devices	(SPK4110-e)
Impact of Pressure Release and Multiple Pressure Fluctuations on Virus Retention Performance	SPK4112-e
Risk Mitigation for Calcium Chloride Solution	SPK4114-e

Publication
Virus Filtration Using a High Throughput Parvovirus Retentive Membrane; Roederstein/Thom, BioPharm International, Aug 2013

Ordering Information

Process Module

3VI	--28	■	C	■	S	F

Filtration area
-M: 2.4 m² | 25.8 ft²
-H: 0.8 m² | 8.6 ft²

Sterilization
-: Prepared for γ
G: γ-irradiated

Mid-Scale Module

3VI	--28	■	C	■	F	O

Filtration area
-F: 0.2 m² | 2.15 ft²
-D: 200 cm² | 0.22 ft²

Sterilization
-: Prepared for γ
G: γ-irradiated

Lab Module

3VI	--28	■	C	G	M	L	■	V

Filtration area
-B: 5.0 cm²
-T: 1.7 cm²

Sterilization
G: γ-irradiated

IT
IT: Integrity tested
–: Not integrity tested

Units per package
V: Two pieces

Accessories & Services

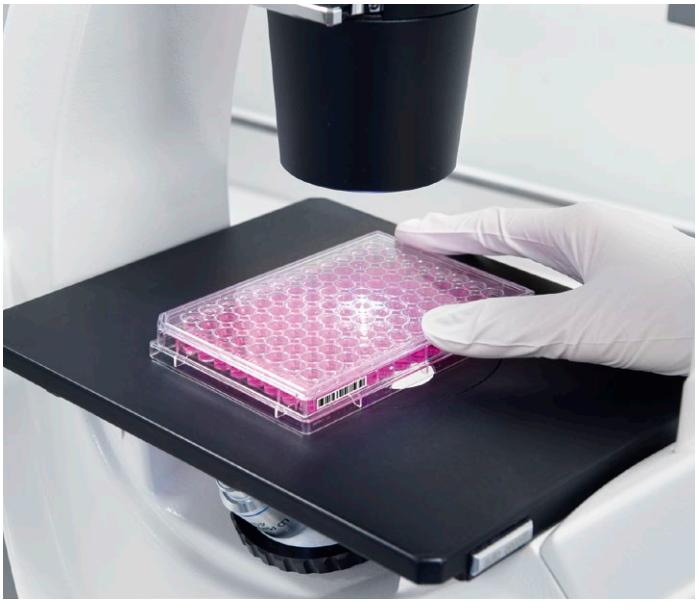
Adsoptive Pre-Filtration
Virosart® Max protects your virus filter irrespective of the process conditions. Virosart® Max will downsize your process and reduce your total virus filtration costs.

Integrity Testing using Sartocheck®
Fully automated Virosart® integrity testing to guarantee intactness of the Virosart® filter applying pre- and post-use diffusion tests.

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 realized by customized single-use or hybrid solutions.



Sartorius Confidence® Virus Clearance Services
Our virus clearance service is the perfect complement to Virosart® HF filters, providing:

- GLP virus clearance studies
- Process design support
- Optimization support

We use a variety of different relevant and model viruses including MVM, MuLV, Reo-3 and PRV. The combination of product and services provides you with a comprehensive virus clearance solution that gives you the confidence you need to proceed.

Sartorius Biologics Testing Services
Your partner to assure an effective virus clearance strategy for your process by MCB | WCB characterization and bulk harvest testing.

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