

Virosart® CPV MaxiCaps® and Cartridges

The 20 nm PESU virus filter for the robust and efficient removal of small non-enveloped and large enveloped viruses



Description

Virus filtration with Virosart® CPV is an integral part of the orthogonal virus clearance technology platform of Sartorius Stedim Biotech. This orthogonal technology platform features virus filtration, virus inactivation and virus adsorption. Virosart® CPV 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 a biopharmaceutical feed stream.

Application & positioning of Virosart® CPV

The main applications for Virosart® CPV for virus filtration are monoclonal antibodies (Mab), antibody fragments (Fab) or small recombinant proteins (<150kD). Virosart® CPV 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.

Product benefits

Virosart® CPV provides highest virus safety to the biopharmaceutical product. This filter retains more than 4 log₁₀ of small non-enveloped viruses (e.g. PPV, MVM) and more than 6 log₁₀ of large enveloped viruses (e.g. MuLV). Based on the unique double layer 20 nm PESU membrane, Virosart® CPV provides excellent flow rates and superior capacity. This filter offers highest virus safety over the entire flow decay profile up to 90%.

Scalability

Scale down work is realised using the Virosart® CPV Minisart (5 cm² capsule) to enable filtration work for flow and capacity studies as well as for GLP virus spiking studies. Scale up studies are performed using Virosart® capsule and | or MidiCaps® (180 cm² | 2.000 cm²) to reliably scale up into larger scale manufacturing. Large scale manufacturing is operated with Virosart® CPV MaxiCaps® or cartridges. Typical batch sizes of products subject to virus filtration with Virosart® CPV MaxiCaps® and cartridges are ≥ 50 liter.

Integrity testing

Virosart® CPV filters are tested for integrity using a water based integrity test with the Sartocheck® 4 technology of Sartorius Stedim Biotech. Virosart® CPV filters have been validated for 4 log₁₀ removal of small non-enveloped viruses using bacteriophage PP7 as the model virus. Validation data is shown in the validation guide of Virosart® CPV.

Quality control

Each individual Virosart® CPV filter is autoclaved and integrity tested during manufacture assuring highest product reliability.

Documentation

Virosart® CPV filters are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Specifications

Materials

Membrane	Double layer polyethersulfone, symmetric
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
Capsule Housing	Polypropylene

Pore Size

CPV (20 nm nominal)

Available Sizes | Filtration Area

MaxiCaps®

Size 1	0.7 m ² 7 ft ²
Size 2	1.4 m ² 14 ft ²
Size 3	2.1 m ² 21 ft ²

Standard filter cartridges

Size 1	0.7 m ² 7 ft ²
Size 2	1.4 m ² 14 ft ²
Size 3	2.1 m ² 21 ft ²

Available Connectors

Sanitary for MaxiCaps® & code 7 for cartridges

Operating parameters

In the direction of filtration	At 20°C (MaxiCaps®) max. 5.0 bar 72.5 psi At 80°C max. 2.0 bar 29 psi
In the reversed direction of filtration	20°C max. 0.2 bar 2.9 psi

По вопросам продаж и поддержки обращайтесь:

Астана+7(7172)727-132, Волгоград(844)278-03-48, Воронеж(473)204-51-73, Екатеринбург(343)384-55-89,
Казань(843)206-01-48, Краснодар(861)203-40-90, Красноярск(391)204-63-61, Москва(495)268-04-70,
Нижний Новгород(831)429-08-12, Новосибирск(383)227-86-73, Ростов-на-Дону(863)308-18-15, Самара(846)206-03-16,
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Extractables

Virosart® CPV filters meet, or exceed the requirements for WFI quality standards set by the USP 26

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

Sterilization

Steaming | Autoclaving:
121°C @ 1 bar | 14.5 psi for 30 min

No In-Line Steam Sterilization of MaxiCaps®!

Technical References

Validation Guide:
SPK5754-e | 85030-522-02
Brochure:
SPK1509-e | 85030-521-89
Virus Information Guide:
SPK5752-e | 85030-521-91

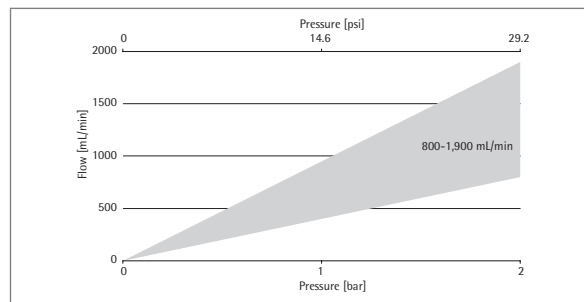
Ordering Information Virosart® CPV Standard Filter Cartridges

545	25	28	V1	Explanation
				Virosart® CPV, double layer
				Adapter 25 S-adapter top, locking bayonet adapter with 226 double O-ring bottom
				Pore Size 28: 20 nm filter membrane
				Height Filtration Area V1: 10" 0.7 m ² 7 ft ² V2: 20" 1.4 m ² 14 ft ² V3: 30" 2.1 m ² 21 ft ²

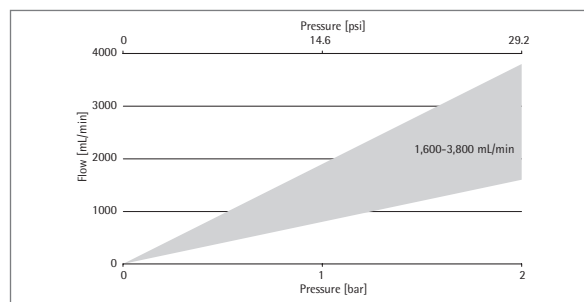
Ordering Information Virosart® CPV MaxiCaps®

545	13	28	V1	--	SS	Explanation
						Virosart® CPV, double layer
						Capsule Design
						Pore Size 28: 20 nm filter membrane
						Height Filtration Area V1: 10" 0.7 m ² 7 ft ² V2: 20" 1.4 m ² 14 ft ² V3: 30" 2.1 m ² 21 ft ²
						Adapter SS Sanitary inlet – and outlet adapter

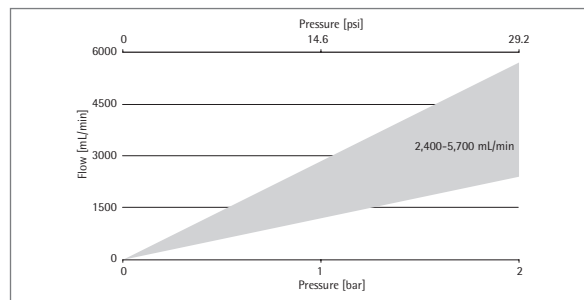
Characteristic Water Flow Rates for Virosart® CPV 10" Standard Filter Cartridges & 10" MaxiCaps®



Characteristic Water Flow Rates for Virosart® CPV 20" Standard Filter Cartridges & 20" MaxiCaps®



Characteristic Water Flow Rates for Virosart® CPV 30" Standard Filter Cartridges & 30" MaxiCaps®



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