Virosart® CPV MidiCaps®

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 $\log_{10}$ of small non- enveloped viruses (e.g. PPV, MVM) and more than 6 $\log_{10}$ 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 cm^2 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 cm^2 | 2.000 cm^2) 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 this Virosart® CPV MidiCaps® are 5 to 50 liter.

Integrity testing

Virosart® CPV MidiCaps® are tested for integrity using a water based integrity test with the Sartocheck® 4 technology of Sartorius Stedim Biotech. Virosart® CPV MidiCaps® have been validated for 4 $\log_{10}$ 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 MidiCap® is autoclaved and integrity tested during manufacture assuring highest product reliability.

Documentation

Virosart® CPV MidiCaps® 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

MidiCaps®

Size 9	0.2 m^2 | 2 ft^2

Available Connectors for Virosart® CPV MidiCaps®

FF	¾" Tri-Clamp (Sanitary) inlet & outlet

Operating parameters

In the direction of filtration	At 20°C (MidiCaps®) 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

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

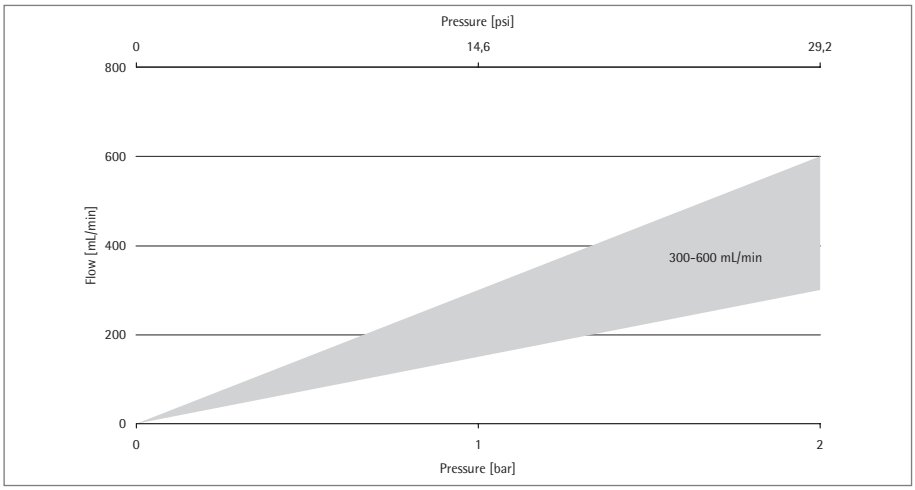
No In-Line Steam Sterilization of MidiCaps®!

Technical References
Validation Guide:
SPK5754-e | 85030-522-02

Brochure:
SPK1509-e | 85030-521-89

Virus Information Guide:
SPK5752-e | 85030-521-91

Characteristic Water Flow Rates for Virosart® CPV MidiCaps®



Order information

	Pore size	Pack size	Test pressure	Max. diffusion
5455328V9--FF--V	CPV (20 nm nom.)	2 MidiCaps®/ box	4.5 bar | 65.2psi	10 ml/min/ MidiCaps®