

Virus Clearance Technologies



Virus
Filtration



UV-
Inactivation



Membrane
Chromatography

CLEARANCE COMPLETED



Virosart[®] CPV
Complete Your Virus
Safety Concept

Virosart® CPV at a Glance

- LRV PPV > 4 log₁₀
LRV Retrovirus > 6 log₁₀
- Highest protein
transmission > 95 %
- Maximized Flow & Capacity
- Disposable technology
- Scalable from 5.3 cm²
to full scale production
- Safe & easy water
based Integrity Test
- Conformance with USP 26



Sartorius Viral Clearance Technologies

The risk of viral contamination is a feature common to all biotechnological products derived from human or animal plasma and mammalian cell lines.

Modern manufacturing processes employ complementary viral clearance technologies, frequently combining active virus removal with virus inactivation steps.

Safety concepts have to guarantee the absence of endogeneous and adventitious viral contaminants through cell line characterization, raw material testing as well as a validated concept for the elimination of any potential viral contaminants within the production process itself.

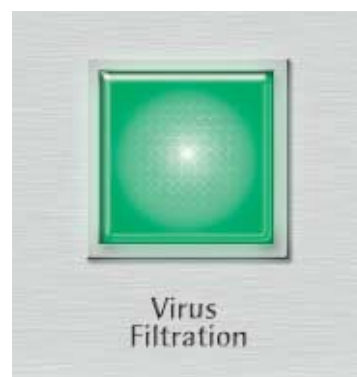
Regulatory guidelines require from these safety concepts to provide overall viral titer reductions in the order of 12 to 20 log₁₀ for the different relevant and model viruses.

Among the various technologies available for viral clearance three robust and orthogonal technologies have been integrated into the Sartorius Virus Clearance Technology Platform.

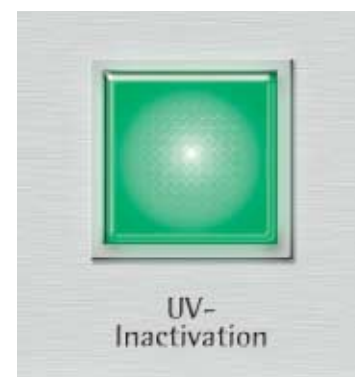
This platform is comprising virus filtration with **Nanofiltration**, virus inactivation with **UVC-light** and **Virus adsorption** with membrane adsorbers. These individual elimination steps are depending on different physical principles and address typical properties of

the relevant virus classes such as size, presence of a lipid envelope and type of the nucleic acid.

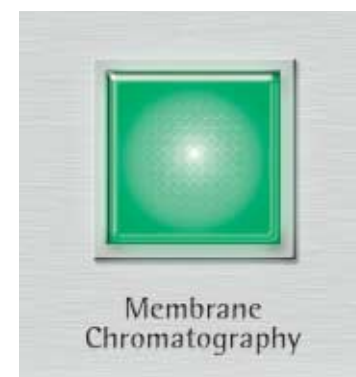
Whether you target the production of therapeutic proteins derived from cell lines or animal/human plasma, Sartorius has the product range that provides you with a total process solution meeting your needs in terms of security, reliability, GMP compliance and cost effectiveness. The 3 step viral clearance technology platform ensures maximum process safety to your manufacturing scheme.



Virosart® CPV virus filter
Virosart® CPV Polyethersulfone filters for state of the art virus retention according to highest safety standards with more than 4 log₁₀ for PPV and more than 6 log₁₀ for retroviruses.



Continuous UVC inactivation
Effective UV irradiation at 254 nm through a novel spiral flow UVivatec module. Highly efficient product mixing and evenly delivered UVC dose for homogeneous and shorter residence time. Ideal for small non enveloped viruses like PPV.



Purification with Membrane Adsorber technologies
Sartobind® Membrane Adsorbers in reusable and disposable formats for the purification of therapeutic proteins, antibodies and clearance of viruses as well as for the removal of contaminants such as DNA, endotoxins or host cell proteins.



Virosart® CPV – Highest Viral Safety & Maximized Process Speed

Virus removal with membrane filtration as an cornerstone of a modern process safety concept has traditionally been accepted as a complementary and robust method for viral clearance.

Virosart® CPV completes the 3 step viral clearance technology platform of Sartorius.

This virus retentive filter features highest virus retention, maximised flow rate & capacity and optimized protein transmission of antibodies or other recombinant proteins.

The new Virosart® CPV filters provide a generic, scalable, state of the art virus retention concept according to highest safety standards with more than 4 log₁₀ for PPV and more than 6 log₁₀ for retroviruses.

Virosart® CPV is being used for virus retention in biopharmaceutical processes as follows:

- Upstream- & downstream processing of biotechnological feed streams
- Downstream processing of human and animal plasma derived products

Virosart® CPV belongs to the Polyethersulfone family of Sartorius and offers the entire range of benefits of this membrane material.

- Highest flow rates and capacity
- Excellent wetting properties
- Easy and safe water based integrity test
- Lowest extractables

Virosart® CPV filters have been validated for 4 log₁₀ removal of bacteriophage PP7. Correlation of IT test data & bacteriophage retention is documented in the validation guide.



Virosart® CPV – Safe & Reliable at Scale Down and Scale Up Level

Reliable scale-down work is of essential importance for viral clearance studies in biopharmaceutical processes.

Clearance- or spiking studies are being performed at external laboratories which have the capability to work with infectious viruses.

Spiking studies in virus filtration require the use of scale down capsules which feature the identical membrane material like the process element as well as they have to operate under the same conditions like the process element, e.g. pressures, flow rates and capacity requirements.

Bench scale & spiking studies are being performed using the Virosart® CPV Minisart or Virosart® CPV Midisart filter capsules.

- Minisart capsules feature 5.3 cm² effective filter area
- Midisart capsules provide 20 cm² effective filter area

As an intermediary scale up step, Virosart® CPV disposable 150 cm² capsules are being used to exactly determine flow and capacity characteristics.

Making full use of this scale down procedure ensures the most reliable and safest process design for small scale and large scale manufacturing.



Virosart® CPV Fulfills USP 26

Extractables

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

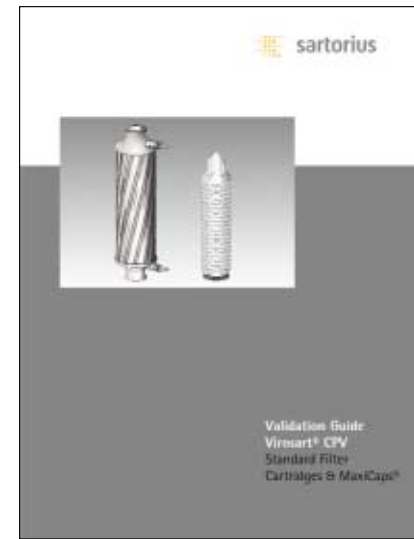
- Non-pyrogenic according to USP Bacterial Endotoxins
- Passes USP Plastics Class VI Test
- Non-fiber releasing according to 21 CFR

Sterilization

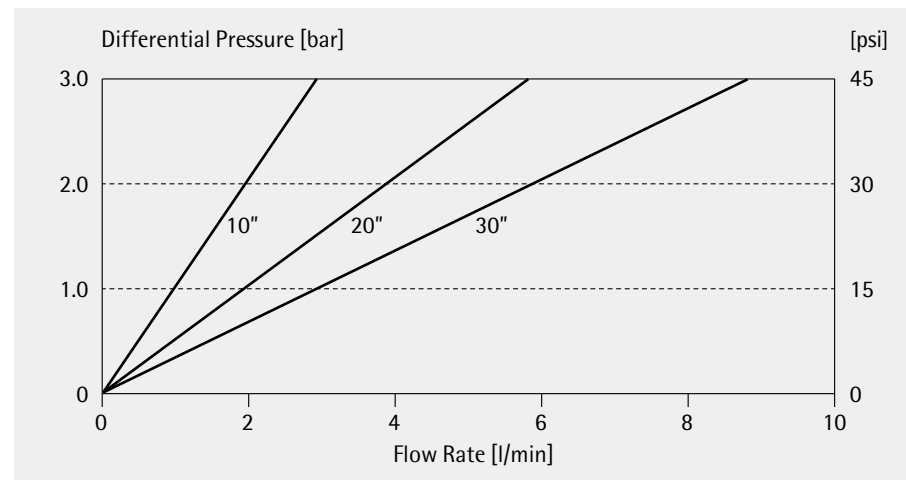
Steaming/ Autoclaving:
121°C, 1 bar | 14.5 psi 30 min
No In-Line Steam Sterilization of MaxiCaps®

Validation documents

The validation guide "Virosart® CPV Standard filter cartridges & MaxiCaps®" provides detailed information on USP specific product performance.

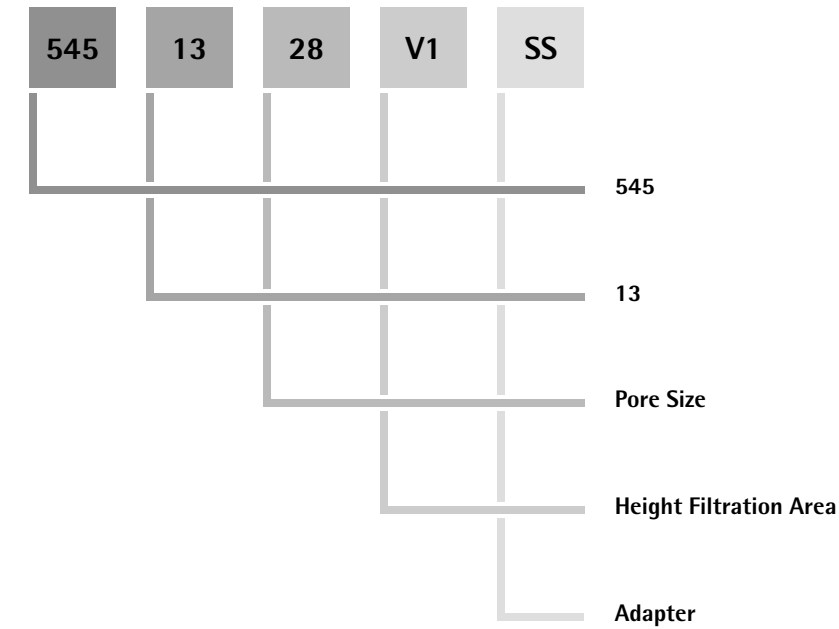


Virosart® CPV Water Flow Rates for Standard Filter Cartridges & MaxiCaps®



Order Information

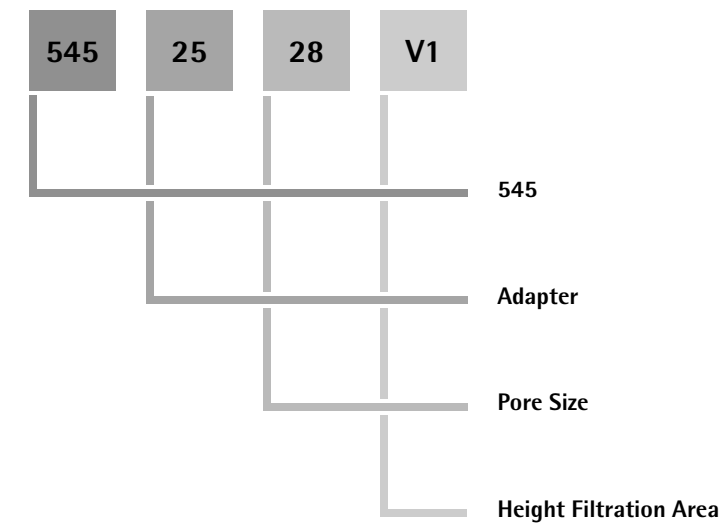
Virosart® CPV MaxiCaps®



Explanation

- 545** Virosart® CPV, double layer Polyethersulfone membrane filter
- 13** Capsule Design
- Pore Size**
28 PPV retentive, 20 nm filter membrane
- Height Filtration Area**
V1 10" 0.7 m² | 7 ft²
V2 20" 1.4 m² | 14 ft²
V3 30" 2.1 m² | 21 ft²
- Adapter**
SS Sanitary inlet- and outlet adapter

Virosart® CPV Standard Filter Cartridges



Explanation

- 545** Virosart® CPV, double layer Polyethersulfone membrane filter
- Adapter**
25 S-adapter top, locking bayonet adapter with 226 double O-ring bottom Pore Size
- Pore Size**
28 PPV retentive, 20 nm filter membrane
- Height Filtration Area**
V1 10" 0.7 m² | 7 ft²
V2 20" 1.4 m² | 14 ft²
V3 30" 2.1 m² | 21 ft²

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