Directions for Use

Virosart® CPV Capsules

Introduction

The purpose of this document is to provide the appropriate method for identifying, installing and using Sartorius Stedim Biotech Virosart® CPV capsules.It must be read in full and stored. Always follow the directions for use.

This document pertains to Sartorius Virosart® CPV capsules with the following part numbers:

Virosart® CPV capsules (box of 5):
- 5451328V4--OO--B
  (½" hose barb connector for inlet & outlet)
- 5451328V4--FF--B
  (¾" triclamp connector for inlet & outlet)

Filtration area

The filtration area of a Virosart® CPV capsule is 180 cm².

Labeling

The type, lot number and serial number are imprinted on the outer support of the housing of the Virosart® CPV capsule. This information is identical to the information found on the label of both the plastic bag and the cardboard box where in addition to type and lot number the order number is indicated.

Rinsing & Determination of Buffer Flow Rate

(In the direction of filtration)

Before using, take care to close the valves of the capsule.

Prior use the filter capsule must be rinsed with buffer at a pressure of 2 bar | 29 psi for 10 min. To make use of the full filtration area the capsule must be vented to render it completely free of air. A hydrophobic PTFE membrane allows air bubbles to escape through the air vent which is positioned at the highest point upstream of the capsule. To do this, briefly open the vent plug and apply the desired filtration pressure.

After the venting procedure, the buffer flow rate can be determined. The buffer flow rate should be around 25 to 50 ml/min at 2 bar | 29 psi.

Autoclaving

Virosart® CPV capsules cannot be in-line steam sterilized. However, sterilization by autoclaving with 2 cycle up to 121°C is possible once the device has been completely wetted in direction of filtration with WFI for 10 – 15 minutes at 2 bar | 29 psi.

Sterilization temperature: up to 121°C, 2 bar | 29 psi. Once the sterilization temperature has been attained the capsules can be autoclaved for at least 30 minutes. The inlet and outlet as well as any open valves should be wrapped with steam permeable autoclave paper. During the autoclave cycle make sure that connecting pieces on the capsule (e.g. made of stainless steel) are not attached too tightly and do not have a tractive effect on the capsule housing which could cause deformation

Integrity Testing

To test the capsules directly before use it us recommended to perform this integrity test after sterilisation. Before sterilisation the capsule must be wetted completely.

The integrity test of a Virosart® CPV capsule must be done using an automated integrity test unit, preferable the Sartocheck® 4 integrity test unit after adequately wetting the filter. When using a Sartorius Stedim Biotech Sartocheck® Integrity Test System, the diffusion tests can be automatically performed, recording the corresponding integrity test data. The max. diffusion value for a Virosart® CPV capsule is 2 ml/min at 4.5 bar. Virosart® CPV capsules require 10 min stabilisation time as well as additional 10 min measuring time for reliable testing. For additional information on how to perform an automatic integrity test please see our Installation and Operating Instructions for the Sartocheck® 4.

Remark

The bubble point cannot be determined for Virosart® CPV capsules because this value will be higher than the maximal allowable differential pressure for these capsules, e.g. 5 bar | 29 psi at 20°C.

Filtration with Virosart® CPV capsules

Virus filtration with Virosart® CPV should be realised at the end of the purification process prior to the last buffer exchange | form and fill. The protein solution which is subject to the virus filtration must be free of aggregates, host cell protein and DNA to avoid premature blockage of Virosart® CPV. These contaminants should be removed either within the initial recovery process or latest by the polishing process of your target molecule. Standard prefiltration prior the virus filtration employs a 0.2 | 0.1 µm Sartopore® 2 membrane filter. The virus filtration should be realised at 2 bar | 29 psi pressure.
The flow rate achieved through the Virosart® CPV capsule during the filtration is a function of the purity of the feed stream, the target molecule size and concentration. The flow rate will decline with the progress of filtration and indicate the respective blockage of the filter.

Maximum Allowable Differential Pressure

In the direction of filtration
At 20°C max. 5.0 bar | 72.5 psi

In the reversed direction of filtration
20°C max. 0.2 bar | 2.9 psi

Changing out the Virosart® CPV capsule

The Virosart® CPV capsule must be changed, when the validated process volume has been processed over the filter or the maximum allowable differential pressure is reached.

Application Support

If required, please contact your Sartorius Stedim Biotech representative to obtain further information on technical data or general information concerning specific applications. Moreover our Application Specialists are available to assist in questions of product and process validation, as well as training of staff and optimization of filtration processes.

Return of used filter elements

If you wish to return used filter elements to Sartorius Stedim Biotech for inspection, it is necessary to decontaminate and sterilize them prior to shipment. This procedure has to be documented in the Return Shipment Form, available from your local Sartorius Stedim Biotech representative. This documentation is required by German law. Returned filter elements cannot be handled unless the appropriate Return Shipment Form is completed.

Liability

Sartorius Stedim Biotech cannot assume liability if Virosart® CPV capsules are subjected to improper use. Please pay particular attention to the directions for use. In the interest of product improvement and | or development Sartorius Stedim Biotech reserves the right to incorporate construction changes into the product.

Thank you for working with Sartorius Stedim Biotech, we appreciate your business.

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List of Sartorius material numbers applying to EPA-FIFRA

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