sartorius stedim biotech

Autoclaving Virosart® Minisart® devices

Application Report #02

Virus Clearance

#06

#03

#04

#05

turning science into solutions

Introduction

Virus retentive filtration (20nm) is a well-established, robust method for the removal of both large enveloped as well as small non-enveloped viruses during the purification process.

In order to validate the efficiency of these filters, a virus spiking study must be performed. For these studies a sterile device is required to avoid contaminations within the cell culture assays (TCID 50) performed for analysis to qualify the retention capacities of these membranes.

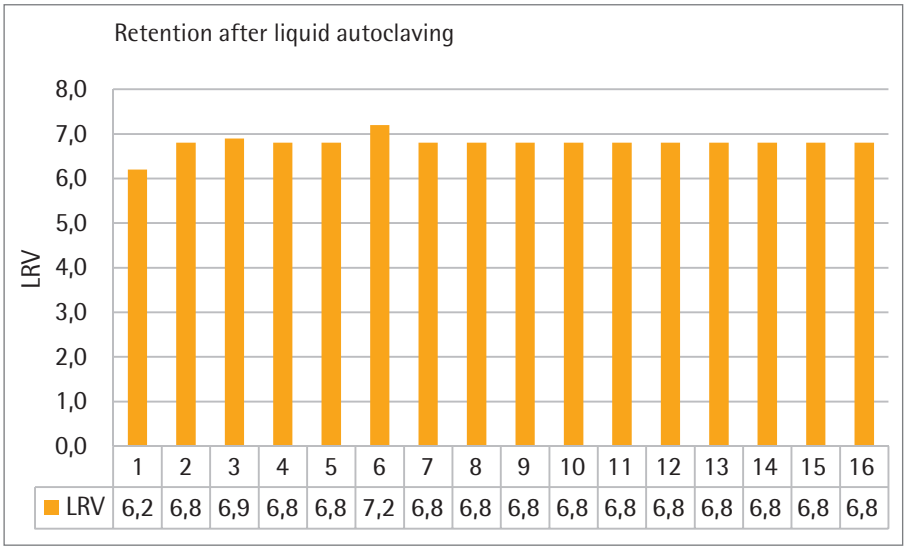
Virosart® Minisart® can be sterilized via autoclaving. These devices are qualified for autoclaving @ 121°C up to 2 cycles. This procedure was successfully tested and qualified during product development.

Like describes within the respective manual the Virosart® CPV Minisart® must be wetted prior to the autoclaving step. After wetting the Virosart® CPV Minisart® is filled with WFI and has to be handled as a liquid filled device. Based on this a liquid autoclaving cycle should be used for sterilization to avoid pressure differences onto the hot membrane. Pressure peaks onto the membrane can lead to membrane damages and with that loss in retentive capacities of the element.

Material & Methods

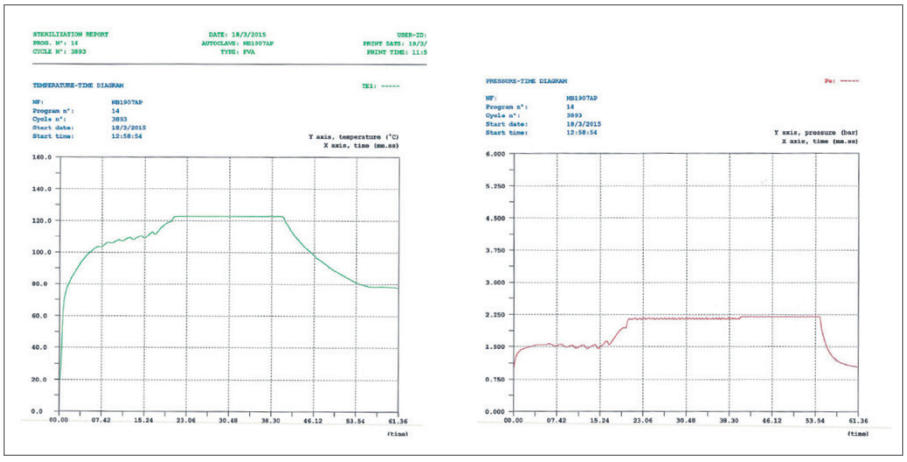
- Virosart® CPV Minisart® were wetted based on the manual instructions and autoclaved @ 121°C for one cycle
- Spiking studies were performed afterwards (within 4h after autoclaving to avoid air bubbles within the device) using bacteriophage PP7, a 20-25nm, non-enveloped ss-RNA Pseudomonas phage (Leviviridae family)
- PP7 is the model virus widely used by filtration manufactures as well as authorities for the evaluation of retention characteristics of virus retentive filters (20nm)
- Determination of the PP7 titer was done by plaques assay at different dilutions

Results

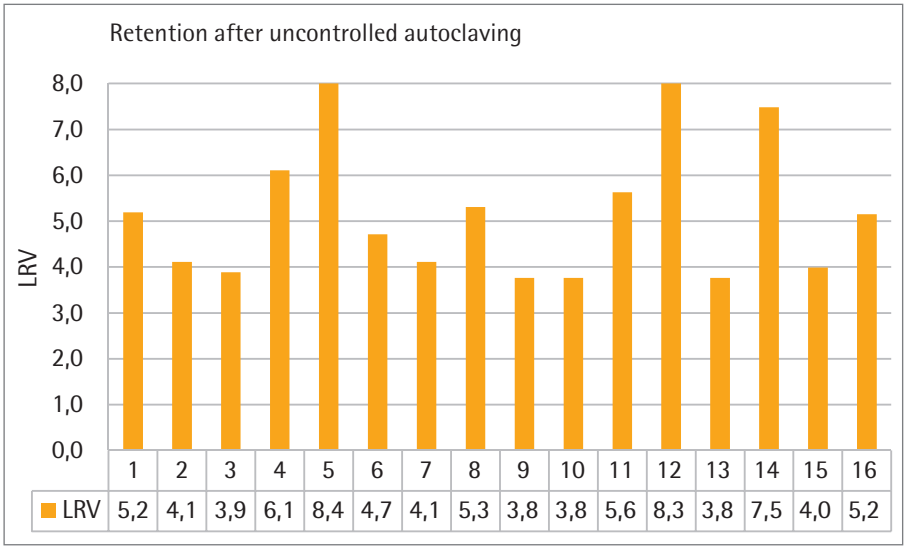


	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
LRV	6,2	6,8	6,9	6,8	6,8	7,2	6,8	6,8	6,8	6,8	6,8	6,8	6,8	6,8	6,8	6,8

Tabelle 1: Virus retentive capacities for Virosart® CPV Minisart® after being autoclaved within a liquid cycle @ 121°C

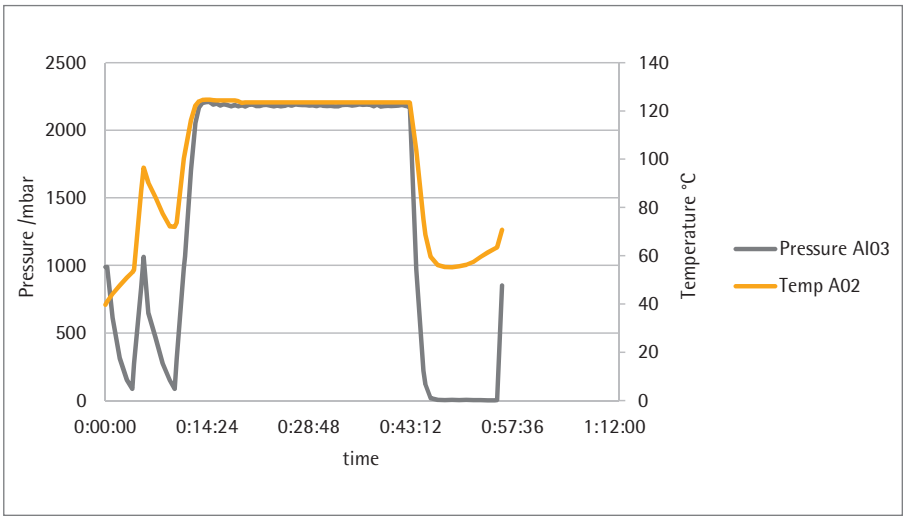


Graph 1: Temperature and Pressure conditions within a standard liquid autoclaving cycle



	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
LRV	5,2	4,1	3,9	6,1	8,4	4,7	4,1	5,3	3,8	3,8	5,6	8,3	3,8	7,5	4,0	5,2

Table 2: Virus retentive capacities for Virosart® CPV Minisart® after being autoclaved within a waste | hardware cycle @ 121°C (uncontrolled pressure peaks)



Graph 2: Temperature and Pressure conditions within a standard waste | hardware cycle

Summary

Virosart® CPV Minisart® reliable retains small non-enveloped viruses (model PP7) at a high level (>LRV 6) after autoclaving within a standard liquid cycle.

Like describes above and within the manual Virosart® CPV Minisart® must be wetted prior to the autoclaving step. With that these devices have to be handled as a liquid filled device and a liquid autoclaving cycle should be used for sterilization. Pressure peaks onto the membrane can lead to membrane damages and with that loss in retentive capacities of the element like shown above.

If the Virosart® Minisart® are autoclaved within a controlled standard liquid cycle eliminating pressure peaks at high temperatures reliable retention is given.

Virosart® HC has to be autoclaved dry with equal rules for the autoclaving cycle (liquid cycle).

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