

Customer Case Study

Virus Clearance Studies Demonstrate Robust Performance of Sartobind® Q at High Loading



Customer Profile

Company Type:
Large Biopharma

Industry:
Health Care

Company Size:
>100K Employees

Customer Challenge

This study was designed to answer three questions. First, the customer wanted to become familiar with the Sartorius Sartobind® membrane adsorbers and evaluate if the product could address current supply issues in the market as part of a second-supplier strategy. Second, the study also needed to identify the maximal possible loading capacity of the Sartobind® adsorbers for four different molecule types to allow future evaluation of costs savings. Finally, the study needed to demonstrate scalability in validation projects by determining if the same high retention results could be achieved with a pico sized (0.08 mL), instead of a nano sized module (1 mL) which would require a smaller amount of product and virus.

Background Information

Membrane adsorber technology is very attractive and effective for virus removal in process development and small-scale clinical manufacturing processes. However, when projects move to large scale manufacturing, using membrane adsorbers which have not been optimized for loading capacity, becomes too costly, and they are normally replaced with resins.

A Pharmaceutical manufacturer sought to explore whether Sartorius Sartobind® membrane adsorbers could be loaded to higher capacities hence, allowing the company to utilize membrane adsorbers at manufacturing scale. Utilizing membrane adsorbers at high loading capacity would save costs on membrane and buffer, shorten process times and replace the tedious column packing | sanitization for the manufacturing scale.

Currently, the company uses a competitor's membrane adsorber, at a loading capacity between 1-5 kg/L (depending on the product). The goal of this loading study was to determine the maximum loading capacity on the Sartobind® Q membrane for four different mAb and mAb-like formats

Provided Solution

The study was split in two parts. One part compared the performance of Sartobind® Nano vs Pico device, and the second part determined the maximum loading capacities for our Sartobind® Q membrane. Sartorius Confidence® Validation Services performed the studies using four different mAb and mAb-like formats provided by the company spiked with Mouse Minute Virus (MMV).

Adsorbers were operated in flow-through mode. Fractions, representing different membrane loadings, were collected and analyzed for the presence of virus. Fraction samples that produced > 4 Log Reduction Value (LRV) retention were pooled with other samples to determine the maximum loading capacity for each product.

Project Key Indicators

Keywords:

- Virus Clearance Studies
- LRV
- Membrane adsorber loading

Project Duration:

- Mid of March 2021 – End of October 2021

Success Criteria:

- Good LRV results (>4)
- Achieve loading capacities > 5kg/L
- Demonstrate equal results using a pico-sized (0.08 mL) vs a nano sized (1mL) device

Provided Solution:

- Scalability & loading study
- Membrane adsorbers challenged with MMV

Result:

- Loading of 20 kg/L for two molecules possible
- LRVs between 4–5 demonstrated
- Better performance than competitor product: For all molecules 1-1.5 more LRV with Sartobind®
- Identical results from Sartobind® Nano and Pico modules



“As a new contract lab, we were honored and excited to collaborate with Sartorius to utilize and evaluate their services and gather important viral clearance data.”

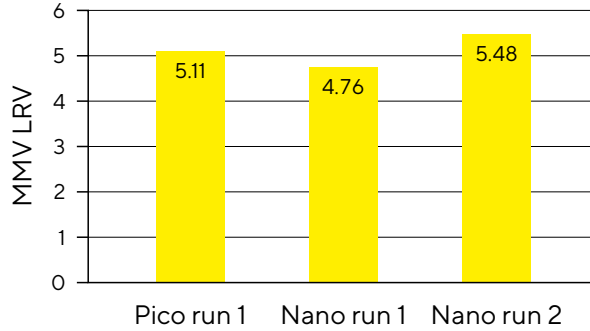
Scientist

Outcome

The results of this study show that both Sartobind® Pico and Nano devices, with 0.08 mL vs 1 mL membrane volumes respectively, reliably show comparable virus retention results when using Fc Bispecific mAb 1. Consequently, Sartobind® Pico devices can be reliably used during virus clearance validation studies, enabling 12.5-fold savings in volume of test material required.

Comparison of Sartobind® Nano vs. Pico Modules

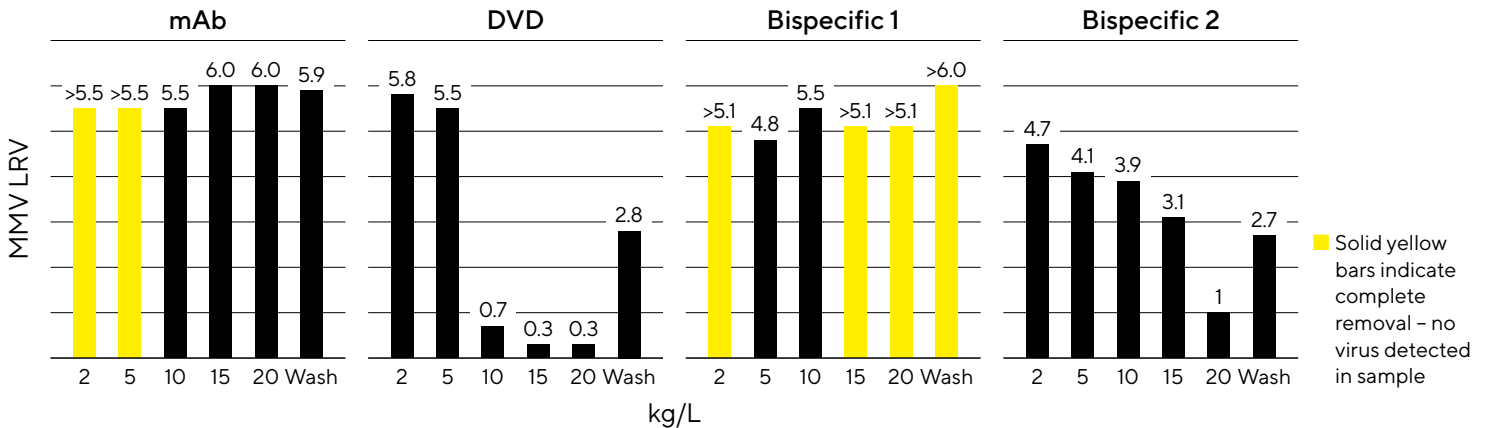
- MMV LRV for nano and pico devices are comparable and show scalability with Fc Bispecific mAb 1
- Builds confidence in using smaller device for virus spiking studies



Note. Sartobind® Q Scalability Study

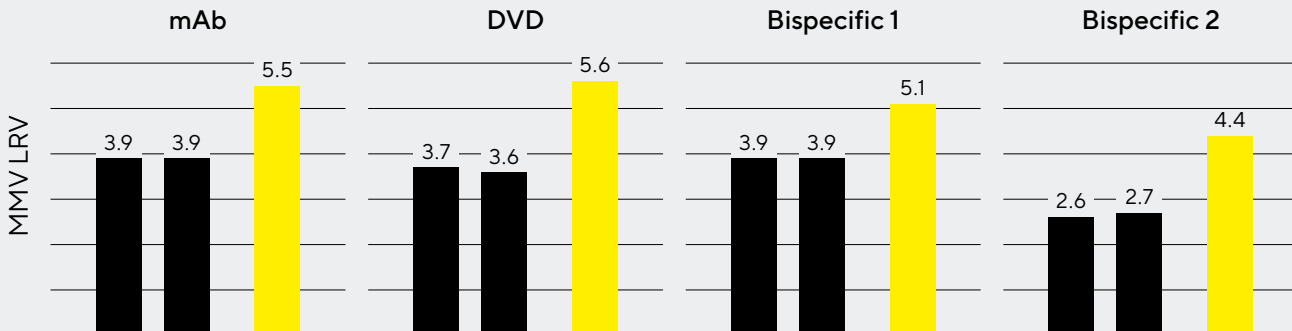
MMV Clearance of the Sartobind® Q Pico (0.08 mL) Fraction Data

- IgG1 mAb and Fc Bispecific mAb 1 showed high LRV up to 20 g/mL loading
- DVD bispecific mAb and Fc Bispecific mAb 2 LRV decreased at loading >5 g/mL



Note. Fractioned Membrane Loading Capacity (kg/L)

Retrospective MMV Clearance Comparison: Sartorius Sartobind® Q vs. Competitor



Note. MMV Clearance Comparison of Sartobind® Q versus Competitor Q Membrane

At a Glance

1-1.5 more
LRVs
with Sartobind® Q

Loading
up to 20 kg/L
for molecules mAb and Bispecific 1

Sartobind® shown to be a
lucrative
alternative



Before Investigational Study

- Loading of 1–5 kg/L
- LRV of 2.5–4
- Membrane adsorber changed to resin for large-scale manufacturing



After Investigational Study


- Using Sartobind® Pico Elements:
 - Reduced customer product volume needed by 12.5×
 - Reduced adsorber costs by 8× during virus spiking studies
- Loading of up to 20 kg/L possible
- LRVs 4–5
- High loading capacities allow for economic use of membrane adsorber for large-scale manufacturing

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 **Optimize Your Loading Capacity With the Help of Our Virus Clearance Experts.**

www.sartorius.com/en/services/validation-service/virus-clearance-validation

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