Application Note

# Scale up with Sartobind® Q pico

**Miniaturized scaleable format for process developers**


## Introduction

Sartobind Q capsules with 4 mm bed height are disposable membrane chromatography devices for polishing of biomolecules in biopharmaceutical production processes.
Sartobind pico (0.08 ml bed volume) is the smallest scalable format in the Sartobind family. The pico has the same 4 mm bed height as the manufacturing scale capsules and scalability was tested through the following parameters:
– Protein binding
– Impurity removal (DNA, endotoxin, host cell protein, bacteriophages)
– Flow rate

The entire Sartobind Q capsule family is listed in the following Table.

Membrane volume (MV) and void volume of Sartobind Q 4 mm capsules

| Sartobind Q 4 mm | Membrane volume (ml) | Nominal void volume (ml) | Nominal void volume (MV) |
|---|---|---|---|
| Pico | 0.08 | 0.4 | 5 |
| Nano | 1 | 5 | 5 |
| Mini | 7 | 20 | 2.9 |
| 5" | 70 | 320 | 4.6 |
| 10" | 180 | 800 | 4.4 |
| 20" | 360 | 1650 | 4.6 |
| 30" | 540 | 2500 | 4.6 |
| Mega | 1620 | 9000 | 5.6 |

## Summary

The aim of this study was to examine whether the Sartobind Q pico meets the performance requirements. All runs were performed with the same membrane lot. Results below indicate that all application requirements are met.

## Results

Before testing binding capacities, devices were sanitized with 1 M NaOH for 30 min at 10 MV/min. Equilibration buffer was 20 mM Tris/HCl pH 7.3 (± 0.1). After sanitization, pH value was checked. The flow rate for all process steps was 10 MV/min.
Lot: Pico 201103D (for BSA studies only: 201104D), Nano 130805063

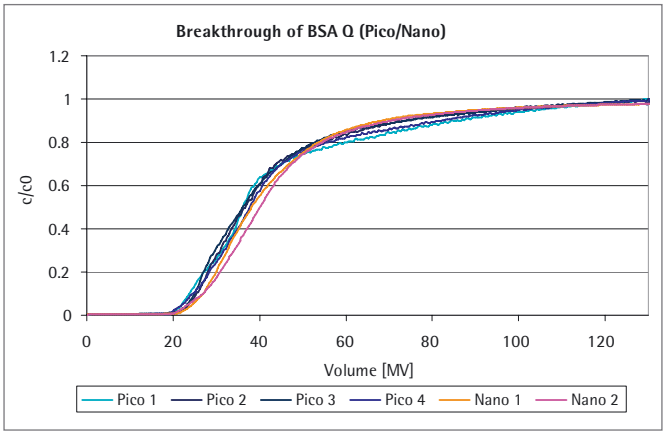
1. Binding of bovine serum albumin (BSA)

Method
– 100 MV Equilibration
– 150 MV Load with BSA in buffer (1 mg/ml)
– 100 MV Wash
– 100 MV Elution with 1 M NaCl in buffer

Dynamic binding capacity at 10% breakthrough:

| Device | [mg/cm²] | Average |
|---|---|---|
| Pico 1 | 0.70 | |
| Pico 2 | 0.70 | |
| Pico 3 | 0.73 | |
| Pico 4 | 0.73 | 0.72 |
| Nano 1 | 0.72 | |
| Nano 2 | 0.71 | 0.72 |

Breakthrough curves:




Comparable performance of Pico with Nano device

2. Binding of DNA

Method
– 100 MV Equilibration
– 150 MV Load with Salmon Sperm DNA in buffer (0.1 mg/mL)

Dynamic binding capacity at 10% breakthrough:

| Device | [mg/cm²] | Average |
|---|---|---|
| Pico 1 | 0.15 | |
| Pico 2 | 0.16 | |
| Pico 3 | 0.18 | |
| Pico 4 | 0.17 | 0.16 |
| Nano 1 | 0.19 | |
| Nano 2 | 0.19 | 0.19 |

3. Endotoxin removal

Method
Endotoxin: LONZA LPS E.coli
Lysate chromogenic: Charles river endosafe Endochrome-K
ß-Glucan blocker: LONZA

- Additional cleaning procedure with NaOH to destroy present endotoxin in the system
- 200 MV Water
- 300 MV Equilibration
- 150 MV Load with endotoxin in buffer (~266 EU/ml)
- Sampling after 50, 100 and 150 MV

Determination of the Log Reduction Value:

| MV | Pico 1 | Pico 2 | Pico 3 | Nano 1 | Nano 2 |
|---|---|---|---|---|---|
| 50 | 3.38 | 3.95 | 3.65 | > 4.35 | 3.73 |
| 100 | 2.93 | > 4.35 | 3.58 | 3.31 | 3.82 |
| 150 | 4.12 | > 4.35 | 3.52 | 3.95 | 3.82 |

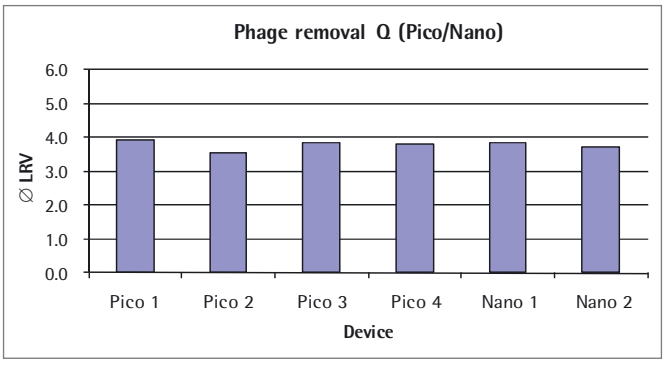
Comparable performance of Pico with Nano device

4. Phage removal

Method
- 300 MV Equilibration
- 150 MV Load with Phage ΦX 174 in buffer (~ 1.34x107 PFU/ml)
- Sampling (after 50, 100 and 150 MV)

Determination of the Log Reduction Value:

| MV | Pico 1 | Pico 2 | Pico 3 | Pico 4 | Nano 1 | Nano 2 |
|---|---|---|---|---|---|---|
| 50 | 4.5 | 3.8 | 4.1 | 4.0 | 4.1 | 4.2 |
| 100 | 3.8 | 3.5 | 3.8 | 3.8 | 3.7 | 3.4 |
| 150 | 3.5 | 3.4 | 3.6 | 3.6 | 3.8 | 3.6 |
| **Average** | 3.9 | 3.6 | 3.8 | 3.8 | 3.9 | 3.7 |




Comparable performance of Pico with Nano device

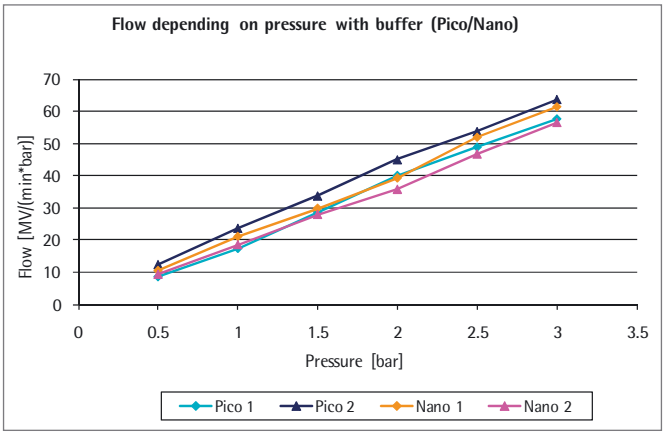
5. Breakthrough behavior with host cell protein

Method
- 100 MV Equilibration
- 100 MV Load with HCP diluted 1 : 50

Binding:

| Device | Binding [mAu × MV] | Average |
|---|---|---|
| Pico 1 | 2158 | |
| Pico 2 | 2150 | |
| Pico 3 | 2125 | 2144 |
| Nano 1 | 2110 | |
| Nano 2 | 2118 | 2114 |

6. Flow rate




Flow rate >10 MV/(min × bar)

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