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Application Note

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Sartocon® Q, tangential flow filtration (TFF), scalability, monoclonal antibody (mAb) purification, ultrafiltration | diafiltration (UF | DF), Hydrosart® membrane, high product yield, process development, high-concentration formulations, process efficiency, downstream processing

Scalability of Sartocon® Q Hydrosart® 30 kDa mAb for Monoclonal Antibody Purification

Marvin Machava, Dr. Marc Jenke, Anika Manzke
Sartorius Stedim Biotech, August Spindler Str. 11, Göttingen

Contact: anika.manzke@sartorius.com

Abstract

The Sartocon® Q Hydrosart® 30 kDa mAb is a next-generation tangential flow filtration cassette designed for robust, scalable ultrafiltration | diafiltration in monoclonal antibody (mAb) manufacturing. This application note demonstrates the scalability of Sartocon® Q from process development to commercial manufacturing, with consistent performance across a wide range of scales (86 cm^2 – 6.18 m^2). Data from internal Sartorius studies and customer trials show that the Sartocon® Q Hydrosart® 30 kDa mAb delivers high product yields (up to 99.2%), enables final mAb concentrations up to 235 g/L, and maintains process times within a standard 8-hour shift. Its robust design, optimized channel geometry, and Hydrosart® membrane technology ensure reproducibility, efficiency, and regulatory compliance for modern bioprocessing needs.

For more information, visit
sartorius.com/tff-cassettes

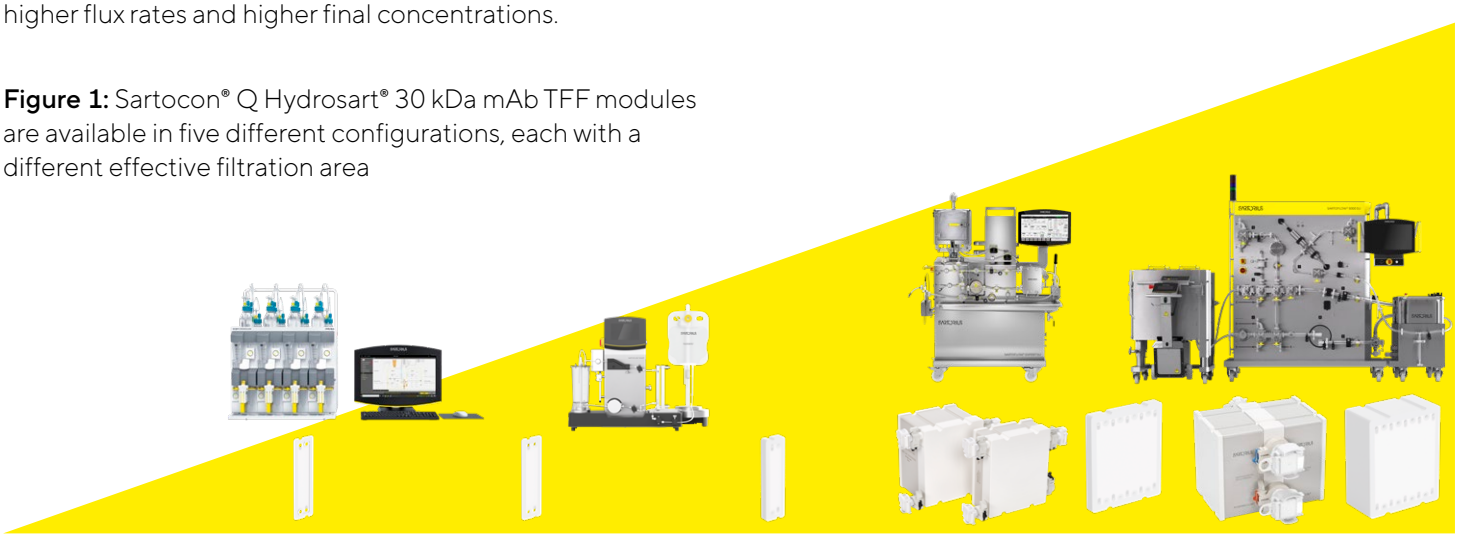
Introduction

The increasing demand for high-concentration monoclonal antibody (mAb) formulations has intensified the need for scalable, robust, and efficient tangential flow filtration (TFF) solutions. The final ultrafiltration | diafiltration (UF | DF) step is essential for achieving target concentrations, enabling buffer exchange, and ensuring product purity.

This application note introduces the new Sartocon® Q Hydrosart® 30 kDa mAb cassette, developed to meet the requirements of the mAb market. Sartocon® Q TFF cassettes are designed to deliver scalability, high yield, and process efficiency in both multi-use and single-use applications. Hydrosart® membranes are designed to ensure stability across a broad pH range, resistance to fouling, and sustained high flux, making them ideal for biological applications, including UF | DF. Available in 2 – 300 kDa molecular weight cut-offs and both single-use and reusable cassette formats, Hydrosart® membranes maintain their integrity and performance over multiple uses without requiring extensive cleaning. Storage and regeneration are easily performed using 0.1 M sodium hydroxide, even at elevated temperatures.

The Sartocon® Q Hydrosart® 30 kDa mAb cassette integrates the optimized Hydrosart® membrane with a novel screen design, offering enhanced efficiency, supporting up to 30% higher flux rates and higher final concentrations.

Figure 1: Sartocon® Q Hydrosart® 30 kDa mAb TFF modules are available in five different configurations, each with a different effective filtration area



Format	Sartocon® Q Slice 100	Sartocon® Q Slice 200	Sartocon® Q Slice	Sartocon® Q	Sartocube® Q SCU
Effective filtration area	86 cm²	688 cm² (4×172 cm²)	0.13 m²	1.26 m² (2×0.63 m²) SCU	6.18 m² (2×3.09 m²)
System	Ambr® Crossflow	Sartoflow® Smart		Sartoflow® Expert SU	Sartoflow® 5000 SU

Note. From left to right: Sartocon® Q Slice 100 Hydrosart® 30 kDa mAb (86 cm^2), Sartocon® Q Slice 200 Hydrosart® 30 kDa mAb (172 cm^2), Sartocon® Q Slice Hydrosart® 30 kDa mAb (0.13 m^2), Sartocon® Q Hydrosart® 30 kDa mAb (0.63 m^2), Sartocube® Q Hydrosart® 30 kDa mAb (3.09 m^2). SCU = self-contained unit.

Materials

The scalability of the Sartocon® Q Hydrosart® 30 kDa mAb was evaluated using a model mAb (IgG) in a series of laboratory- and pilot-scale TFF experiments. The study was designed to reflect typical process development and manufacturing conditions for mAb purification, with a focus on demonstrating consistent performance across a wide range of membrane surface areas and system formats.

All experiments were performed using Sartocon® Q Hydrosart® 30 kDa mAb cassette or a competitor module (88 cm^2; operated on the Ambr® Crossflow system). The cassettes were assembled in four different system configurations, representing increasing scales (Figure 1): Ambr® Crossflow (86 cm^2), Sartoflow® Smart (688 cm^2), Sartoflow® Expert SU (1.26 m^2), and Sartoflow® 5000 SU (6.18 m^2). Both multi-use and single-use device formats were included to reflect the diversity of modern bioprocessing environments.

Methods

The feed solution for all trials consisted of a downstream process intermediate mAb (IgG) at a starting concentration of 15 g/L. The loading density was standardized at 1,000 g/m^2 for all scales and cassettes. Concentration (UF1), diafiltration (DF), and final concentration (UF2) processes were executed.

In the first ultrafiltration step (UF1), the product was concentrated to an optimal diafiltration point of 75 g/L, determined during prior process development. This was followed by seven diavolumes of buffer exchange (DF), performed at constant feed flow and transmembrane pressure (TMP), with feed flow controlled by a pump and TMP maintained via a retentate valve. For the Sartocon® Q Hydrosart® 30 kDa mAb, a crossflow rate of 500 LMH and TMP setpoint of 1.0 bar were used throughout all scales. The competitor was operated at a crossflow rate of 540 LMH and TMP of 1.1 bar, under which its best performance was observed.

The second ultrafiltration step (UF2) further concentrated the product to a final target of greater than 200 g/L. During UF2, the systems were operated at constant feed pressure of 1.8 bar with the retentate valve fully open, ensuring that the resulting TMP corresponded to the optimal value for the respective filter type. This approach allowed for the highest possible crossflow rate at the optimal TMP, maximizing process efficiency while minimizing the risk of membrane fouling and product aggregation.

Throughout all experiments, process parameters such as feed flow, TMP, and pressure were continuously monitored and recorded. The total process time, including all UF and DF steps, was measured for each scale, with the goal of maintaining the entire operation within a standard 8-hour production shift. Product yields were determined at each stage by measuring protein concentration in the harvest, blowdown, and post-flush fractions using UV absorbance at 280 nm. Final product concentrations were confirmed by analytical size-exclusion chromatography and compared across all scales.

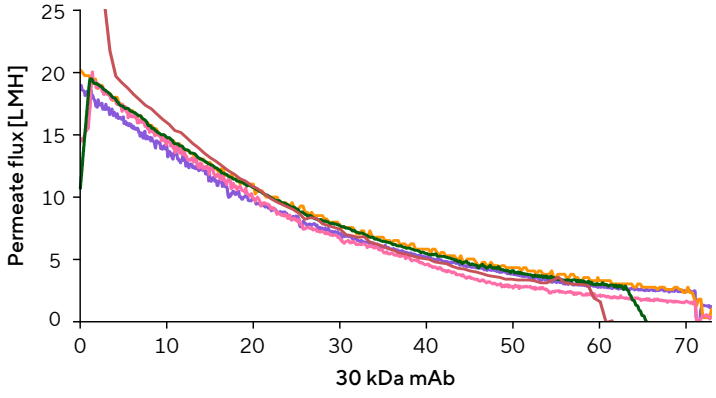
All equipment was cleaned and sanitized according to Sartorius standard operating procedures prior to use. Data analysis was performed using GraphPad Prism and Microsoft Excel. The study design and reporting followed the International Society for Pharmaceutical Engineering (ISPE) recommendations for process scalability and reproducibility.

Results

The scalability of the Sartocon® Q Hydrosart® 30 kDa mAb was systematically evaluated using a model mAb (IgG). Four different device scales (Sartocon® Q Hydrosart® 30 kDa mAb 86 cm², 688 cm², 1.26 m², and 6.18 m²) and an 88 cm² competitor module were tested. The two larger scales were tested as a single-use self-contained unit within respective single-use systems, whereas the two smaller scales were tested as conventional multi-use devices.

The process was designed to mimic industrial UF | DF operations, with UF1 performed up to an optimal DF point (75 g/L) and seven diafiltration volumes, followed by UF2 to achieve concentrations exceeding 200 g/L. All UF1 and DF steps were operated at constant feed flow and TMP, while UF2 was conducted at constant feed pressure with the retentate valve open, ensuring the TMP remained at the optimal value for the respective filter type. Across all tested Sartocon® Q Hydrosart® 30 kDa mAb formats, an inlet pressure of 1.8 bar with the retentate valve fully open resulted in identical TMP values. This demonstrates the exceptional scalability of channel and device geometry.

Figure 2: Permeate flux (LMH) over time during UF2, from the four Sartocon® Q Hydrosart® 30 kDa mAb cassette formats and a competitor cassette, each operated on a scale-appropriate TFF system



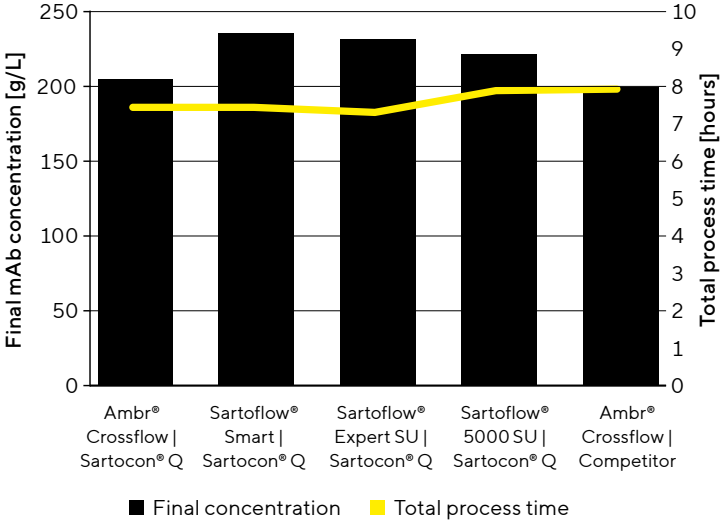
Sartocon® Q Hydrosart® 30 kDa
- 86 cm² Ambr® Crossflow
- 6.18 m² Sartoflow® 5000 SU
- 688 cm² Sartoflow® Smart
- 1.26 m² Sartoflow® Expert SU

Competitor
- 88 cm² Ambr® Crossflow

The flux curves for each scale were highly consistent, indicating that the hydrodynamic conditions and membrane performance were preserved from the smallest (86 cm²) to the largest (6.18 m²) device (Figure 2). The overlap of the flux curves is a hallmark of robust scalability in TFF systems, and confirms that Sartocon® Q can be reliably scaled without loss of performance or process control.

Process times were also consistent across scales (Figure 3). The total process duration, encompassing UF1, diafiltration, and UF2, remained below the critical threshold of 8 hours for all device sizes. This operational window is significant, as it aligns with the standard shift length in biomanufacturing and ensures that the entire UF | DF process can be completed within a single production shift, minimizing the risk of product degradation and maximizing facility throughput.

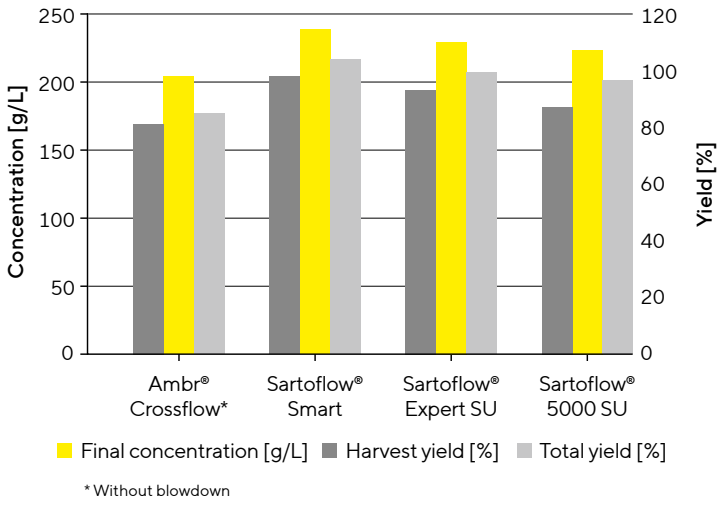
Figure 3: Total process time (h) and final mAb concentration (g/L) for Sartocon® Q Hydrosart® 30 kDa mAb and competitor cassettes



Yield and product concentration were key performance indicators in this study. The final mAb concentrations achieved with the Sartocon® Q Hydrosart® 30 kDa mAb reached up to 235 g/L, demonstrating the cassette's ability to support high-concentration formulations required for modern therapeutic antibodies (Figure 3). Primary harvest yields ranged from 93.5 to 97.6% across all scales, excluding Ambr® Crossflow runs because no blowdown was performed. Total yields, including a post-flush step, achieved an average mAb recovery of 99.2% (Figure 4).

Discussion

Figure 4: Primary harvest and total yields achieved with Sartocon® Q Hydrosart® 30 kDa mAb across scales



These results indicate that the Sartocon® Q Hydrosart® 30 kDa mAb enables efficient product recovery and minimizes losses throughout the process. The competitor module barely reached the target concentration of 200 g/L within the process time target, indicating that it was operating close to its performance limits under the given conditions.

The process requirements set at the outset—specifically, the loading density of 1,000 g/m^2 and the maximum process time of 8 hours—were met in all cases. The robust design and optimized channel geometry of the new cassette type facilitated consistent performance, regardless of scale or system configuration. Notably, the trial included both multi-use and single-use formats, and the results were reproducible across these operational modes.

In summary, the new cassette design exhibited seamless scalability, high yield, and robust process control across a broad range of device sizes. These results confirm the cassette's suitability for both process development and commercial manufacturing, supporting its application in high-value biotherapeutic production.

The Sartocon® Q Hydrosart® 30 kDa mAb demonstrated scalable, consistent performance and high yield across a broad range of process scales. Its channel geometry and robust Hydrosart® membrane make it a versatile solution for both process development and commercial manufacturing. The new cassette design enables high final concentrations at reasonable crossflow rates, with fast process times and high product recovery, outperforming the competitor module.

The design of the Sartocon® Q minimizes product degradation, supports high-viscosity solutions (3–30 cP @250LMH feed flux), and ensures process times remain within a standard shift. Its scalability is confirmed by the overlapping flux curves and consistent yields across all tested scales, verifying its suitability for modern mAb workflows.

Conclusion

The Sartocon® Q Hydrosart® 30 kDa mAb demonstrates exceptional scalability and robust performance across a broad range of device sizes, from 86 cm^2 to 6.18 m^2. The results confirm that the Sartocon® Q family maintains high product yields and enables high final mAb concentrations, regardless of scale or when comparing multi-use and single-use configurations. Importantly, all process requirements—including standardized loading density and completion within a single production shift—were consistently met. These findings validate the Sartocon® Q Hydrosart® 30 kDa mAb as a reliable and efficient solution for mAb purification, supporting both process development and commercial manufacturing while ensuring regulatory compliance and operational flexibility.

Additional Resources

Sartorius. (2025). *Sartocon® Q Hydrosart® 30 kDa mAb: Fast and efficient monoclonal antibody processing* [Datasheet] https://api.sartorius.com/document-hub/dam/download/300916/Sartocon-Q-Hydrosart-30-kDa-mAb-Datasheet-en-B.pdf

Sartorius. *TFF cassettes.* https://www.sartorius.com/en/products/process-filtration/tangential-flow-filtration/tff-cassettes

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Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Göttingen
Phone +49 551 308 0

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

For more information, visit
sartorius.com

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