

AxiChrom columns

Intensify downstream bioprocessing



Unlock process intensification

The goal for biopharmaceutical manufacturers is to develop a process that will deliver material for clinical trials quickly and smoothly, achieve success in these trials, and scale up to commercial manufacturing. Traditionally, column packing has been considered a bottleneck. Suboptimal packing is not only time-consuming, but can result in poor performance. By eliminating these two concerns, you can focus on the core process.



Purposeful design...

The AxiChrom™ platform was designed for this purpose: to help you achieve efficient and reliable protein purification at all scales. We combined our long experience within chromatography with innovative design solutions for bioprocessing. This work resulted in robust, sanitizable, and automated columns that enable fast start-up, reproducible results, as well as maximized uptime (Fig 1). By choosing the right column from the start, you can significantly impact the overall process costs and results.

...and proven performance...

An optimally packed bed is key to the purification process. With AxiChrom columns, a single operator can reach this goal at the touch of a button. All thanks to preprogrammed, verified, and automated packing. AxiChrom columns have an outstanding performance and they are already part of many FDA-approved manufacturing lines globally. In other words, you can feel confident your process will deliver reliable results time and again.

...delivers process intensification opportunities

To help you maximize productivity and facility utilization, AxiChrom columns are optimized for modern chromatography resins, like Capto™ and MabSelect SuRe™ families. The columns can also be used with, for example, automated slurry tanks and Media Handling units. In short, AxiChrom columns enable high-capacity protein purification with easy technology transfer and a small footprint.

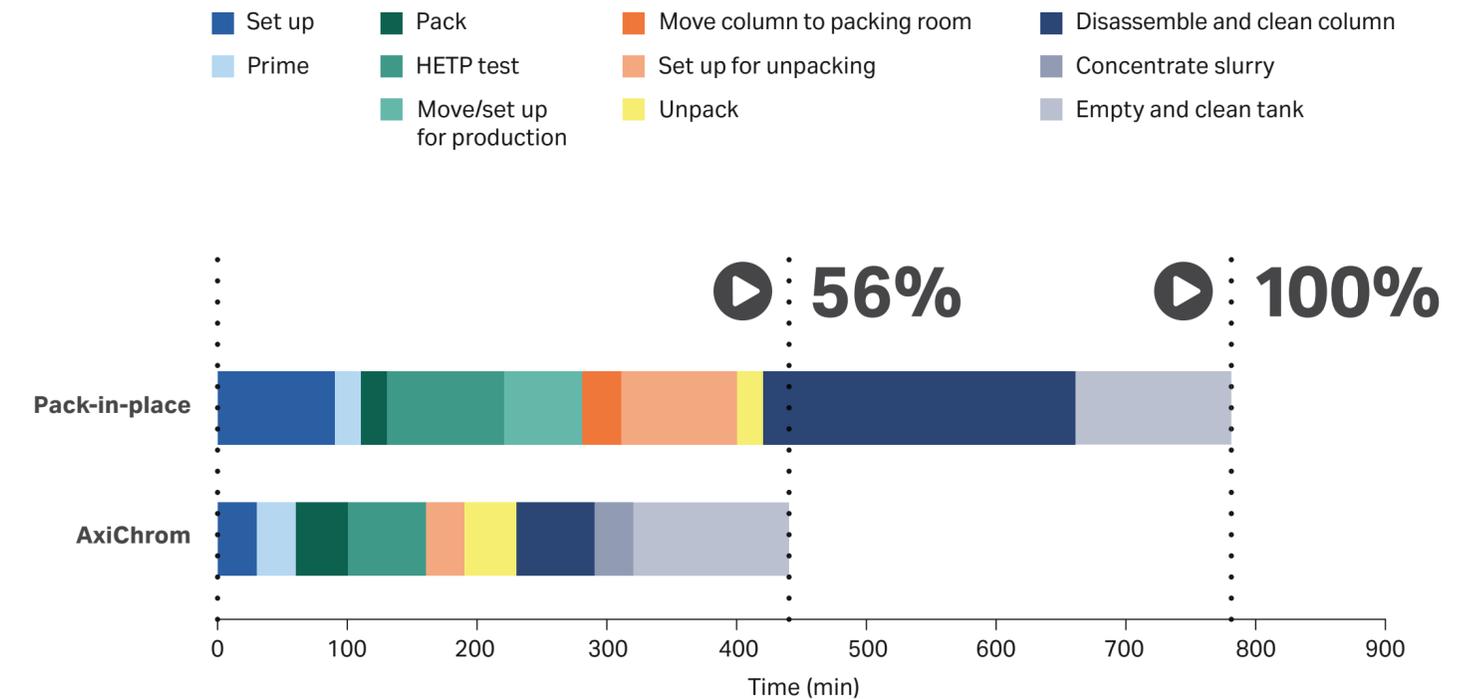


Fig 1. Packing, unpacking, and maintenance of an AxiChrom column only takes 56% of the time required for a traditional column. Successful packing at first go ensures that labor, resin, and water costs are reduced. An optimally packed, stable bed together with straightforward handling and maintenance will also give secured uptime in operation. Data from Cytiva assessment studies.

Gain efficiency through design

Striving for highly productive, cost-efficient processes is a constant challenge. Uptime needs to be kept to a maximum and product safety is of the highest priority. To help you meet these challenges, we have implemented several technical advances and years of experience into the purposeful design of AxiChrom.

Fast start-up

Columns need to be packed quickly and reliably at all scales, demanding minimal set-up and operator time. With AxiChrom, straightforward handling and a limited need of extra equipment help you get off to a quick start. Reduce time spent on packing and repacking through automated packing using verified methods and axial compression technique.

Scalable reliability

Along with axial compression and preprogrammed packing, achieving an optimally packed bed also requires an efficient liquid distribution system. AxiChrom columns have a patented distribution system with a design optimized for maximal net area and efficient flow. An even distribution of liquid throughout the column delivers several key purification benefits, like high yield, great resolution, and low elution volumes. The same technology is used across the range of columns, so you can expect excellent performance and reliable results at all scales.

Easy sanitization

The efficient flow of liquid throughout the column have more benefits. Together with other creative design solutions, such as an efficient flow path and a priming groove, it enables minimized dead space and air pockets. Also, manual handling is kept to a minimum as the column, slurry tank, and chromatography system are connected in a closed system. This innovative column design allows for very high standards of hygiene, essential to columns used in cGMP environments.



Related literature

Application note: Sanitization and endotoxin clearance in AxiChrom columns (28929042)

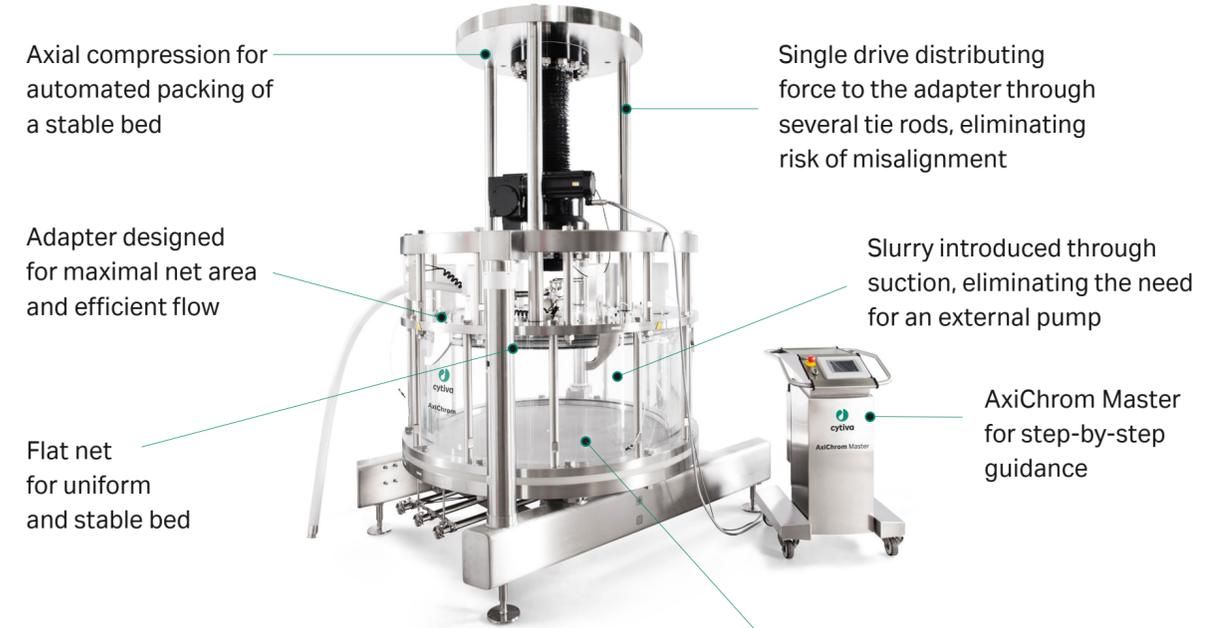


Video

How to pack large-scale AxiChrom chromatography columns
[cytiva.com/bioprocess](https://www.cytiva.com/bioprocess)

The purposeful column design will help you maintain bioburden control, gain efficiency, and maximize uptime.

Ensuring an optimally packed bed



Enabling easy sanitization



Rely on predictable results

To avoid costly surprises in late phases, columns need to perform consistently at all scales during process development. The ability to predict the separation performance and operational parameters at final production scale is vital for success. The proven performance of AxiChrom will help you achieve reliable results throughout this process.

In-built knowledge

To show the outstanding performance, we have verified packing in the different AxiChrom column sizes with our commonly-used BioProcess™ resin platforms (Table 1). Taking it one step further, we loaded this knowledge into AxiChrom as Intelligent packing, ready-to-use packing methods. With these methods, excellent packing results can be achieved independent of operator experience.

Reproducible results

The automated packing enables great reproducibility (Fig 2) and easy transfer of methods between facilities. Operator independence also allows fast product changeover within a facility or to a contract manufacturing organization (CMO). So regardless of experience or location, users can expect the same great separation efficiency.

Real scalability

AxiChrom columns deliver reproducible results over the entire column range as the distribution systems ensure uniform flow through the bed, irrespective of size (Fig 3). As the process moves through resin screening, and into process development, the choice of scalable column platform becomes more important. AxiChrom diameters range from 50 to 1600 mm for exceptional processing all the way.

 **Related literature**
Data file:
AxiChrom columns
(28929041)

 **Related literature**
Application note: Predictable scale-up
through column design and robust packing
methodology (28949052)

Selecting a scalable column with a proven performance can make a significant difference in the whole process chain.

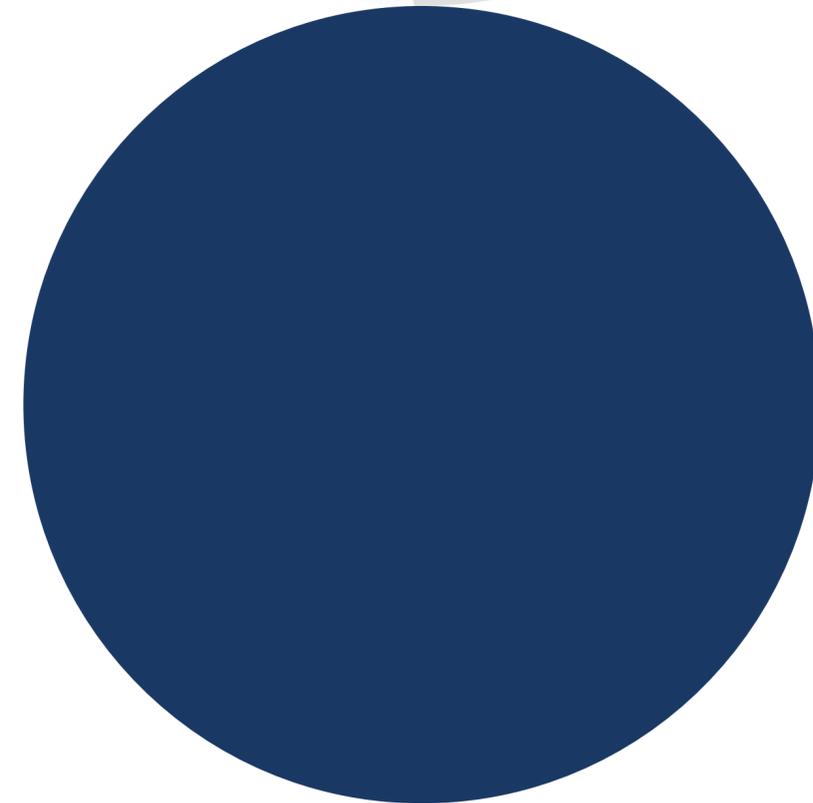


Table 1. Data extracted from verification studies performed on AxiChrom columns with a selection of BioProcess resins, showing efficient results throughout the range

Resin	Column diameter (mm)	Bed height (cm)	N/m ^{1,2}	h ^{1,3}	A _s ^{1,4}
SP Sepharose™ Fast Flow	70	30	7200	1.5	1.0
	100	30	7700	1.4	1.0
	140	30	6400	1.6	1.1
	200	10	7000	1.5	1.2
	400	30	7100	1.6	1.2
	1000	30	6000	1.9	1.2
MabSelect SuRe	300	20	8100	1.4	1.1
	400	20	8300	1.4	1.1
	600	20	8200	1.4	1.2
	1000	20	7300	1.5	1.1
	1600	20	6100	1.8	1.2
Capto S	50	20	6500	1.6	1.0
	100	40	7100	1.4	1.0
	200	40	7300	1.4	0.9
	400	10	5300	2.1	1.3
	1000	15	7000	1.5	1.2
	1600	20	4700	2.4	1.3

¹ N/m, h, and A_s results are average values from three to five packings.

² N/m = plate number per meter

³ h = reduced plate height = HETP/particle diameter

⁴ A_s = asymmetry factor

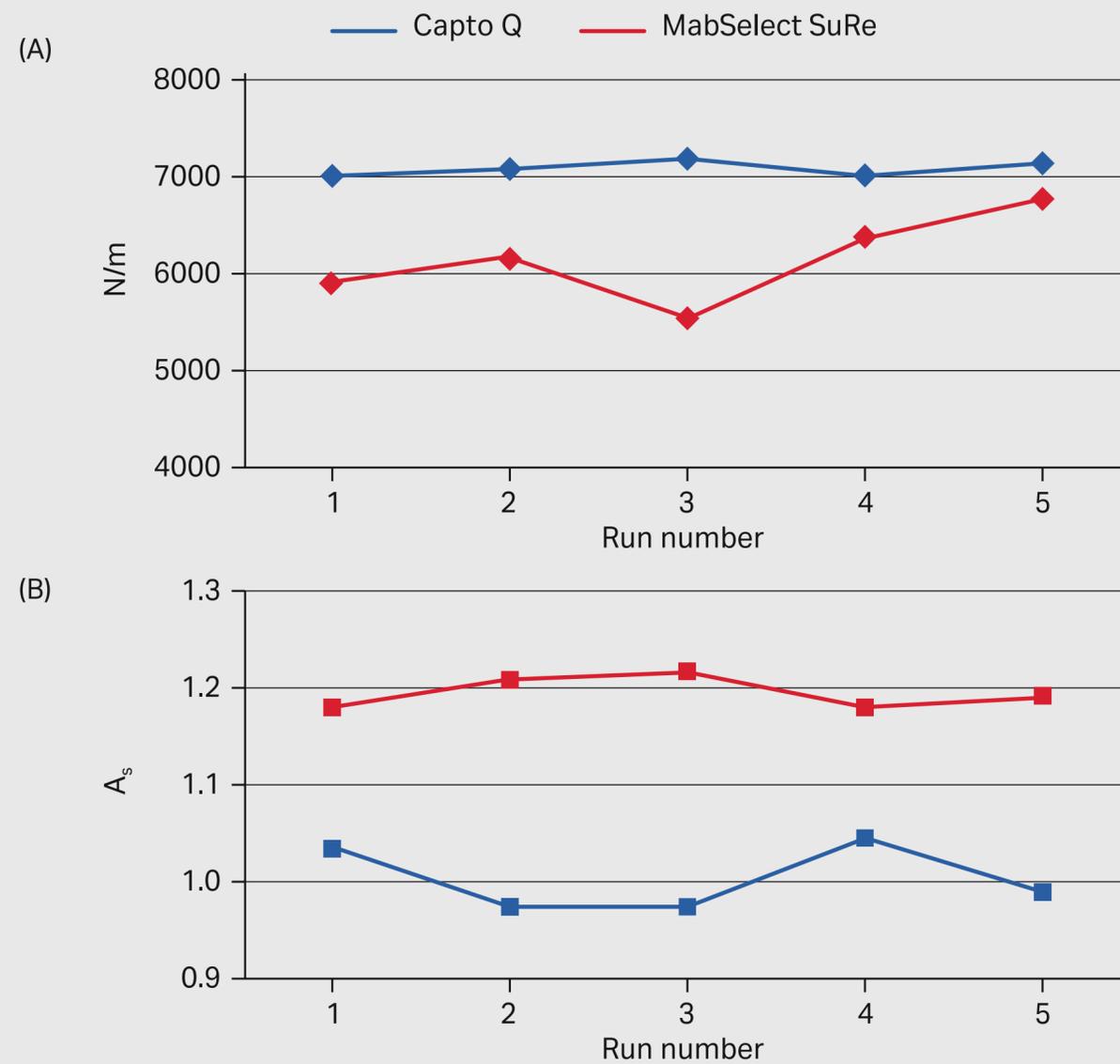


Fig 2. AxiChrom columns show excellent reproducibility independent of operator or column size. Repeated packings, by two to three different operators, of Capto Q in AxiChrom 50 at 40 cm bed height and MabSelect SuRe packed in AxiChrom 1600 at 20 cm bed height. The degree of variation in plates per meter (N/m) and asymmetries (A_s) is similar in AxiChrom 50 and 1600 columns, demonstrating both reproducibility and scalability.

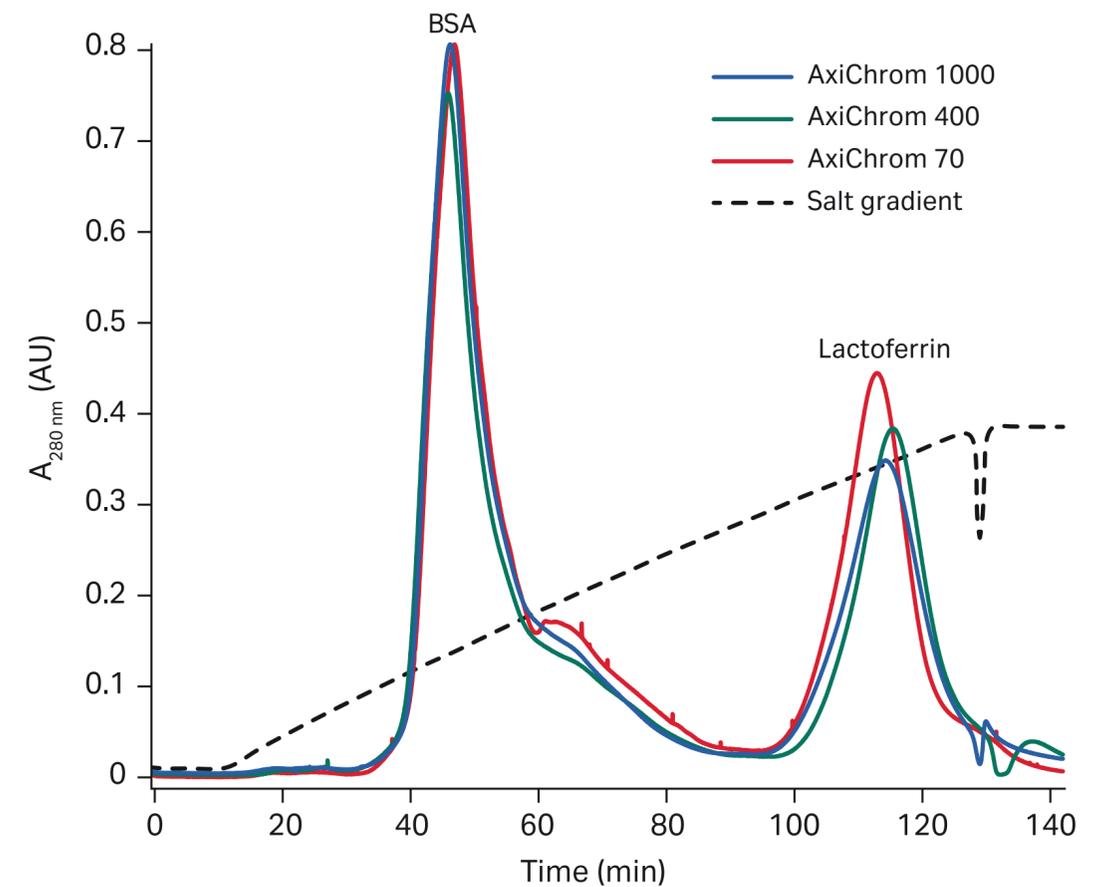


Fig 3. Separation of bovine serum albumin (BSA) and Lactoferrin on SP Sepharose Fast Flow in different AxiChrom columns demonstrates real scalability within the AxiChrom platform.

Access high productivity

Overall process intensification is essential for a more cost-efficient downstream process. Modern chromatography resins are designed for high capacity, high liquid velocities, and a high number of operational cycles. AxiChrom columns let you use the full capacity of such resins.

Full capacity

Flexibility in process design is beneficial for process economy. AxiChrom columns accommodate the broad windows of operation of modern resins (Fig 4). The wide range of operation for high-flow agarose resins, such as Capto and MabSelect SuRe, is supported by the design of AxiChrom columns. Running your process at high flow velocities and bed heights allows for excellent productivity in a small footprint.

Robust performance

Both our BioProcess resins and AxiChrom columns perform with a high degree of efficiency over many processing cycles, displaying very high stability. As an example, AxiChrom columns can use the full liquid velocity of modern resins, even at large column diameters (Fig 5). To further improve process efficiency, AxiChrom columns are designed to minimize resin loss. An exact amount of resin can be automatically packed without an external pump.

Automated efficiency

Our ÄKTA™ chromatography systems support AxiChrom columns throughout scales. In process development, ÄKTA avant system brings efficiency to method development. UNICORN™ control software and Intelligent packing will guide you through method creation, set-up, and maintenance of all AxiChrom columns. At large-scale manufacturing, the level of automation can be increased by linking AxiChrom to an ÄKTAprocess™ system and an automated slurry tank. The units can also be integrated into a higher automation system, such as DeltaV™ Distributed Control System.

 **Related literature**
Application note:
Packing MabSelect™
and MabSelect SuRe
media using verified
methods (11000752)

 **Related literature**
Application note:
Packing Capto S, Capto Q,
and Capto DEAE in
production-scale columns
(28925932)

 **Related literature**
Procedure:
Packing Capto S
ImpAct using
verified methods
(29143803)

Together, AxiChrom columns, BioProcess resins, and ÄKTA systems can deliver increased productivity and facility utilization through process intensification.

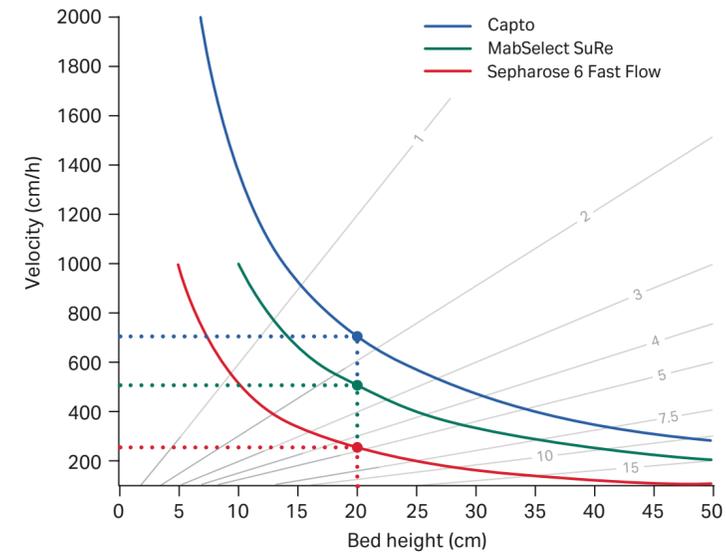


Fig 4. Operating ranges for Capto and MabSelect SuRe compared with Sepharose 6 Fast Flow resin. The highly rigid Capto and MabSelect SuRe base matrices allow a much larger window of operation (area below the curves) at large scale than previous generation of agarose-based resins, such as Sepharose 6 Fast Flow. This is particularly true at bed heights of 20 to 30 cm and above. Data correspond to a 1000 mm diameter column, at 20°C and viscosity of water. Red, green, and blue curves correspond to pressure limits of 1, 2, and 3 bar, respectively. Grey contours give the residence time in the column in minutes.

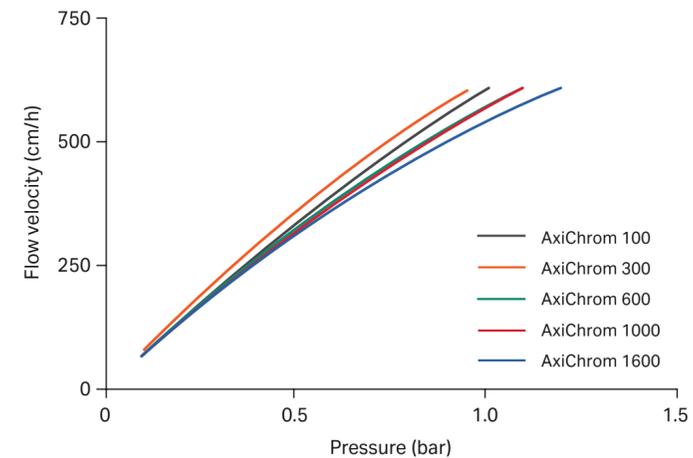


Fig 5. Regression curves of pressure-flow tests for MabSelect SuRe in 20°C water at 20 cm packed bed height in AxiChrom 100, 300, 600, 1000, and 1600 equipped with stainless steel bed supports. Pressure/flow curves provide a simple, yet effective illustration of column and resin performance in terms of the maximum velocity at which the process can be run. MabSelect SuRe can be run at 500 cm/h with a back pressure of less than 2.0 bar. System/tubing pressure is excluded.

Accelerate your bioprocess journey

At Cytiva, we have invested in chromatography resins, column design, and column packing methods to ensure reliable results throughout the entire process. Our solutions work together, from start to finish, to help you achieve operational efficiency, drive down costs, improve productivity and yields, while also providing manufacturing agility. We have a wide range of solutions to further support you in your biopharmaceutical projects.

Facilitating validation

To simplify validation and reduce start-up time, comprehensive product documentation is available for all AxiChrom column sizes. The product documentation includes extractables and leachables data, general specifications, and assembly drawings. IQ/OQ documentation is also available. These regulatory support measures help speed up planning and implement cGMP manufacturing.

Service

Equipment used in cGMP environments need to be qualified before use, and periodically evaluated to confirm that they are maintained in a validated state. To secure excellent performance and maximized uptime, we have built in serviceability into our equipment from the development stage. AxiChrom columns are supported by a comprehensive suite of spare part and maintenance services, enabling the columns to run in peak condition.

Sustainable security of supply

We have several solutions in place to assure secure supplies of critical BioProcess resins. For instance, our strategic reserve secures deliveries of chromatography resins to registered customers in case of unexpected events that affect our manufacturing. For systems and columns we have spare parts locker and other service contracts in place to secure maximum processing uptime.

Fast Trak

Global Fast Trak provides a broad range of process development support in upstream and downstream for biopharmaceutical production and clinical phase I and II biomanufacturing. Additionally, Fast Trak offers training and education services in the same area. Practical project support and advice from Fast Trak can help you plan, implement, and document upstream and downstream processes from start-up to clinical manufacturing, while training your personnel at the same time.

Custom BioProcess solutions

We also design and manufacture customized products to meet your requirements for equipment that are not part of our standard offering. AxiChrom columns with 1800 and 2000 mm diameter are available through Custom BioProcess solutions.



Video

Overview of AxiChrom chromatography columns



Video

How to maintain large-scale AxiChrom columns



Video

How to pack small-scale AxiChrom chromatography columns



Video

How to maintain small-scale AxiChrom chromatography columns

Pre-clinical

Clinical manufacturing

Full-scale manufacturing

Chromatography systems



ÄKTA avant



ÄKTApilot™



BioProcess Modular 1/4"



ÄKTAprocess



BioProcess Modular 2"

AxiChrom columns



AxiChrom 50-200



AxiChrom 300-450



AxiChrom 600-1600



AxiChrom Master 300-1600

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