

QuikScale® Biochromatography Columns

Innovative chromatography columns for scalable, rapid purification

Biopharmaceutical manufacturers increasingly require tools that maximize process yields, boost productivity, and shorten time-to-market. To meet these demands, the scalable family of QuikScale® columns delivers greater product purity at faster linear velocities than columns currently used in most pharmaceutical processes. As a part of our total solution, these innovative columns have been designed to be used easily with any biochromatography system, such as our Mobius® Chrom 20 system, from small scale pilot processes through complex development and manufacturing operations.

Ultra high throughput with all media types

Designed to achieve ultra high throughput, robust QuikScale® columns are easily, uniformly packed to deliver optimal resolution across a wide range of chromatographic applications, accommodating all media types. The innovative flow distributor assures full, uniform media utilization within the column, assuring reproducible and reliable separations. Using the high flow option with operating pressures up to 7 bar, flow rates up to 1000 cm/hr are achievable enabling greater process design flexibility by allowing greater bed heights when utilizing media with high flow and/or backpressure requirements.

Benefits

- · High linear velocity for maximum productivity
- Easy to pack and unpack
- Rapid scale-up with a full range of column size from 70 mm to 630 mm
- Multiple tube materials that suit a wide variety of applications
- Maximum flexibility change tube material and height in minutes





Fast packing and unpacking

Column packing, processing, and unpacking are performed faster and with less effort. There's no heavy lifting or complex disassembly involved; all components remain attached to the column. An optional removable lower end-cell makes unpacking simple and quick. The simple design eliminates the need for tools and hoists during packing and unpacking.

A yoke and central screw mechanism supports the flow distributor, ensuring this assembly easily moves during packing and unpacking. The flow distributor makes it easy to pack uniform beds. The flow distributor can be swiveled to afford easy access for maintenance without the need to lift the adjuster assembly from the column.



Flow distributor seal technology ensures reliable, fail-safe operation

To make packing simple and efficient, the seal is spring force actuated and uses air to deactivate the seal. This design offers smooth vertical movement, and allows the flow distributor assembly to be gently positioned and secured, without disrupting the packed bed.



The bed support, which is available for 10 µm,

 $20~\mu m$, and $30~\mu m$ sizes, consists of stainless steel mesh screens that enhance flow distribution efficiency. The screens, unlike plastic supports, allow the passage of air without requiring pre-wetting.

Predictable, scalable performance

Column materials and geometries were carefully chosen to ensure consistent chromatographic performance from lab scale to production. QuikScale® columns are available in nine diameters from 70 mm to 630 mm. Stainless steel mesh screens, flow cells and column tubes for each column diameter are made of the same materials and are designed to ensure reliable performance across the range of column diameters. Column materials, a unique seal design, and optimized flow distribution, all contribute to creating predictable, scalable processes.

Choice of three column tube materials, for any application

QuikScale® columns meet a broad range of applications. Tubes are offered in three materials:

- Cast acrylic, resistant to breakage with improved ethanol resistance and low protein binding
- Glass, suitable for a wide range of process application
- Stainless steel for improved corrosion resistance and high cleanability

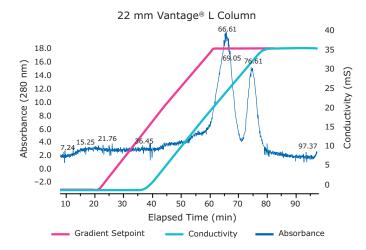
All materials used in the manufacture of the column that come into contact with the process stream conform to relevant sections of the FDA Code of Federal Regulations Volume 21, parts 170 to 199, or have passed USP Class VI tests for toxicity.

Dependable construction for longlasting, reliable performance

Durable frame design and construction, as well as robust tube materials ensure excellent physical stability to deliver years of trouble-free operation. Specially developed tube manufacturing technology results in excellent tube quality on a consistent basis. This reliability, throughout the QuikScale® column product line, is important for generating reproducible performance critical in pharmaceutical manufacturing.

Modular design

A full line of accessories and installation kits enables quick set-up. Versatile configurations make it easy to adapt columns for use in multiple process applications.



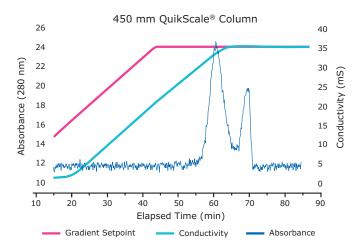


Figure 1. Quick and reliable scale-up

Separation of ovalbumin from trypsin inhibitor was scouted on a Millipore Vantage® L column (22 mm). The process was then linearly scaled up (418X by volume, 20X by diameter) to a 450 mm QuikScale® column with highly comparable results.



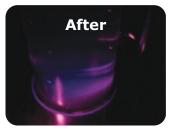


Figure 2. Before and after images of riboflavin presence (green) in a 100 mm QuikScale® column

Glass 100 mm and acrylic 450 mm Quikscale $^{\rm @}$ columns were challenged with a concentrated riboflavin solution and subsequently cleaned with 0.5 M NaOH.

Chemical resistance of QuikScale® Columns

Chemical compatibility chart Specification Sheet - 20513903

Simple and convenient to clean and operate

QuikScale® columns are designed for clean-in-place (CIP), low maintenance, and sanitary operation. Smooth surface finish minimizes entrapment of contaminants and prevents corrosion. The elimination of O-rings in product contact areas prevents unswept surfaces, providing better cleanability.

A riboflavin clearance test performed on QuikScale® columns demonstrated that they can be effectively sanitized. Glass 100 mm and acrylic 450 mm Quikscale® columns were challenged with a concentrated riboflavin solution and subsequently cleaned with 0.5 M NaOH. The observable removal of riboflavin (Figure 2) indicates that there are no dead flow areas within the Quikscale® columns and that all areas are swept with sufficient and consistent velocity.

Ordering information

QuikScale® Columns - GA and GS Range

The QuikScale® column is available in two different configurations. For applications that require frequent packing and unpacking, the column may be ordered with a removable end cell (GA) and optional transport dolly. For applications that require infrequent packing a fixed bottom end cell is available (GS).

Standard QuikScale® Columns			Catalogue Number		
Column Diameter (nominal)	Material	Pressure Rating (bar)	Tube Length		
			550 mm	800 mm	1100 mm
70 mm	Acrylic	7	GA071711	GA071712	GA071713
			GS071711	GS071712	GS071713
	Glass	7	GA072711	GA072712	GA072713
			GS072711	GS072712	GS072713
100 mm	Acrylic	7	GA101711	GA101712	GA101713
			GS101711	GS101712	GS101713
	Glass	7	GA102711	GA102712	GA102713
			GS102711	GS102712	GS102713
140 mm	Acrylic	7	GA141711	GA141712	GA141713
			GS141711	GS141712	GS141713
	Glass	6	GA142611	GA142612	GA142613
			GS142611	GS142612	GS142613
200 mm	Acrylic	7	GA201711	GA201712	GA201713
			GS201711	GS201712	GS201713
	Glass	4.8	GA202511	GA202512	GA202513
			GS202511	GS202512	GS202513
250 mm	Acrylic	5	GA251511	GA251512	GA251513
			GS251511	GS251512	GS251513
	Stainless	5	GA253511	GA253512	GA253513
			GS253511	GS253512	GS253513
300 mm	Acrylic	5	GA301511	GA301512	GA301513
			GS301511	GS301512	GS301513
	Glass	3	GA302311	GA302312	GA302313
			GS302311	GS302312	GS302313
	Stainless	5	GA303511	GA303512	GA303513
			GS303511	GS303512	GS303513
350 mm	Acrylic	5	GA351511	GA351512	GA351513
			GS351511	GS351512	GS351513
	Stainless	5	GA353511	GA353512	GA353513
			GS353511	GS353512	GS353513
450 mm	Acrylic	5	GA451511	GA451512	GA451513
			GS451511	GS451512	GS451513
	Stainless	5	GA453511	GA453512	GA453513
			GS453511	GS453512	GS453513
630 mm	Acrylic	3	GA631321	GA631322	_
	Stainless	3	GA633321	GA633322	_

Spare parts and accessories

The QuikScale® columns are complemented by a range of spare parts and accessories, including:

- · High flow kit
- Process valves
- Connection kits
- Seals, clamps and adapters
- Bubble traps
- · Column tube kits
- Replacement parts

Please refer to the Spare Parts list (70, 100, 140 mm) – MK_SS4989EN – for more information.

Support for your application needs

We have the know-how to provide you with everything you need for your process development applications. Technical briefs describe the benefits you will acquire when using the QuikScale® columns. For more information, call our Technical Service department or ask your Application Specialists for in-depth technical notes. An operator's manual contains full details of components, packing, testing, procedures for cleaning and sanitizing, troubleshooting and the spare parts list.

QuikScale® Chromatography

Columns Featuring Industry Leading Chromatography Resin

Eshmuno[®] Resin

A unique family of ion-exchange, mixed-mode, and affinity resins specifically designed for highly productive downstream purification

Fractogel® Resin

Tentacle modified synthetic polymer resins for ion exchange, size exclusion, and metal chelate affinity.

ProSep® Ultra Plus Resin

High dynamic binding capacity protein A affinity chromatography media, designed for cost-effective, large-scale purification of today's higher titer therapeutic antibodies.

Related Systems to Support your Chromatography Process



CoPrime® Biochromatography Process-Scale Systems

The CoPrime® biochromatography systems (CoPrime® 20 L up to 1200 L/h and CoPrime® 40 L up to 2500 L/h) are designed to achieve optimum separation and purification of monoclonal antibodies, vaccines, plasma, and therapeutic proteins. The systems support rapid scale-up and are ideally suited for pilot and process scale.



Mobius® Chrom 20 System

The Mobius® Chrom 20 System is a flexible, automated, single-use chromatography system that enables consistent and reliable separation and purification of mAbs, vaccines, plasma, and therapeutic proteins at clinical and process scales. The system delivers optimal operational flexibility for processes up to 2000 L with flow rates up to 20 L/min and enhanced isocratic and gradient accuracy.

MilliporeSigma 400 Summit Drive Burlington, MA 01803

To place an order or receive technical assistance

In the U.S. and Canada, call toll-free 1-800-645-5476 For other countries across Europe and the world, please visit: **EMDMillipore.com/offices** For Technical Service, please visit: **EMDMillipore.com/techservice**

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