

## Datasheet

# Chromabolt<sup>®</sup> prepacked chromatography columns

Chromabolt<sup>®</sup> prepacked columns are a family of pre-validated columns prepacked with Merck Millipore chromatography resins, designed for early clinical stage manufacturing. Available in 3 sizes – 10, 20 and 32 cm inner diameter (i.d.), these prepacked columns free up end users valuable time and resources by eliminating manual packing and cleaning. With Chromabolt<sup>®</sup> prepacked columns, you can spend your time on manufacturing your products and not on laboriously packing chromatography resins.

Merck Millipore's Chromabolt<sup>®</sup> prepacked columns have been designed for use with our comprehensive chromatography resin portfolio. Using our proven resins, automated column packing equipment and our extensive column packing knowledge, we can ensure that these prepacked columns will safely arrive at your facility within specification.



## Chromabolt® prepacked columns have been intelligently designed for ease of use in manufacturing facilities

- Column has been robustly designed to withstand damage in everyday use
- Effortlessly transportable by a single person
- Fully ergonomic and designed with Environmental Health & Safety (EH&S) considerations
- Easily accessible inlets and outlets
- Simple exterior cleaning and wiping
- 20 cm and 32 cm i.d. columns on castors
- Compatible with all currently available chromatography systems and connections

With Chromabolt® prepacked columns, you will also benefit from the following:

1. Elimination of laborious packing
2. Fast set-up time compared to traditional columns
3. No cleaning of hardware required
4. Sized for pilot plant applications and small batch manufacturing
5. No additional capital investment or spare parts required



## Time Savings: Column economics

The advantages of fast turnaround time for Chromabolt® columns are illustrated in figure 1 where the hours required for setup and cleaning of traditional hardware column is compared to a prepacked column.

### INDUSTRY AVERAGE HOURS

Data aggregated from industry sources.

Manual  
Prepacked

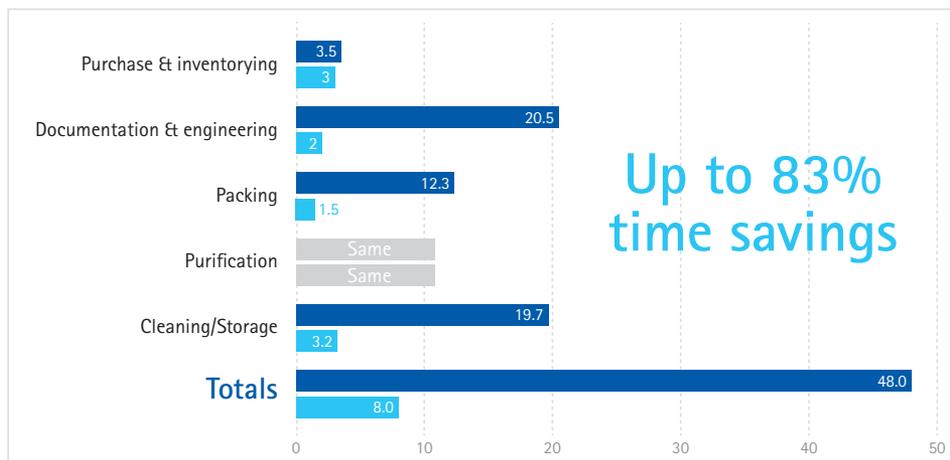


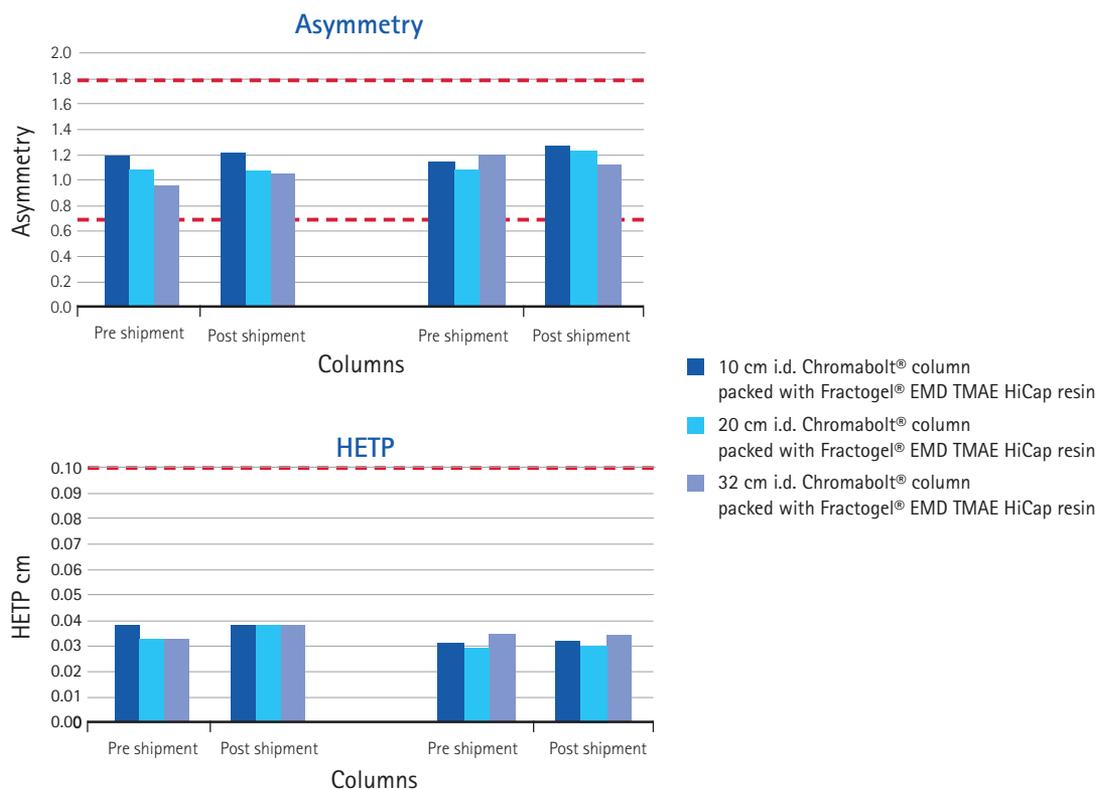
Figure 1. Estimated time savings assuming packing of resin is successful on the first try.

## Shipping Studies

Critical to providing robust prepacked chromatography columns is the assurance that the columns will maintain resin specifications during shipping. Our extensive testing has demonstrated that we maintain a consistent packed bed at all three column sizes no

matter what the shipping environment Chromabolt® columns are subjected to. All columns were tested for HETP and Asymmetry pre, and post shipping under the ISTA-1E testing protocol. Results are shown in Figures 2 - 5.

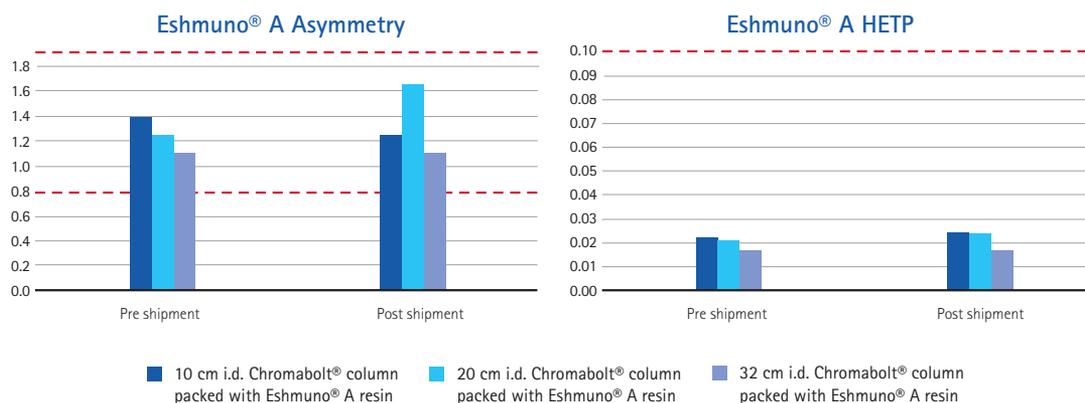
**Figure 2 & 3.** HETP and Asymmetry were tested in 400mM NaCl pre- and post shipping on all three column sizes (data shown for Fractogel® EMD TMAE HiCap resin only). Dashed red lines indicate specification for asymmetry between 0.7-1.8 and HETP of < 0.1cm.



Chromabolt® column shipping has been validated on Fractogel® and Eshmun® base beads. Since the base bead for the Eshmun® A resin is slightly different

from the base bead for Eshmun®, we have done additional shipping validation on this resin in all three sizes.

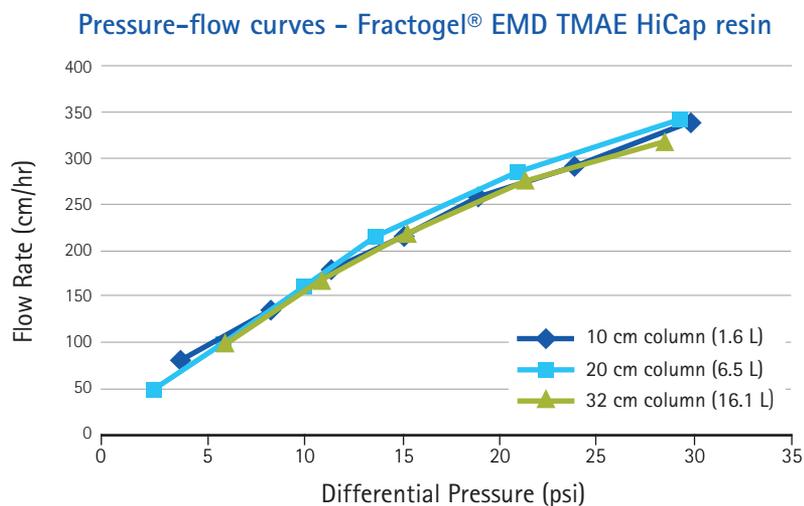
**Figure 4 & 5.** Test results for HETP and Asymmetry pre- and post shipping under the ISTA-1E protocol



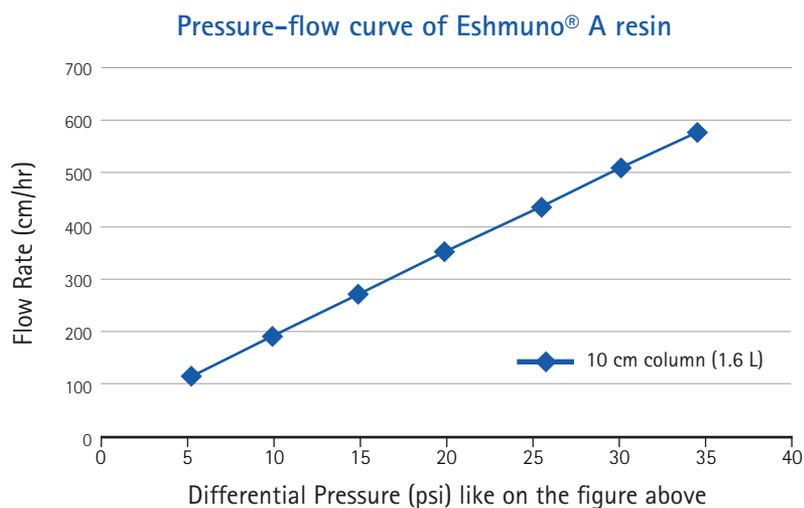
## Scalable Performance and Column Packing: Column Pressure Flow Characteristics

Pressure-flow curves (figure 6) of Fractogel® EMD TMAE HiCap resin measured in 160mM NaCl solution at different differential pressures between the inlet and outlet of the Chromabolt® columns are linear and closely overlaying at all three column sizes. This shows that the columns are scalable in terms of their performance between all three sizes.

Eshmuno® A pressure-flow curve was measured (figure 7) in 160mM NaCl solution between the inlet and outlet of the Chromabolt® 10cm (id) column. The data was linear.



**Figure 6.** Pressure-flow curves were generated in 160mM NaCl and measured at a differential pressure between the inlet and outlet of the column.



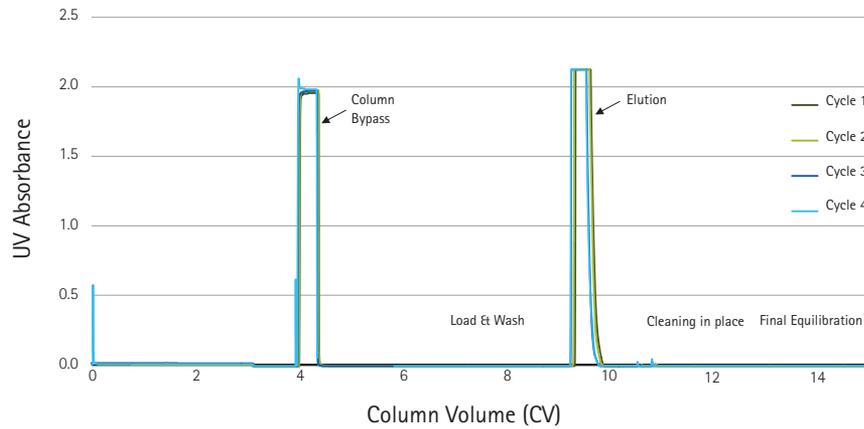
**Figure 7.** Pressure-flow curve of Eshmuno® A resin

## Multiple cycle usage Ion Exchange Resin Study

Chromabolt® 10 cm prepacked columns containing Fractogel® EMD TMAE HiCap resin were loaded with BSA feed streams to approximately 20% of the column volume. The plot below shows the UV chromatogram at 280 nm from four bind-elute cycles.

The overlaying traces indicate reproducible and robust bed performance over multiple uses. The column asymmetry, HETP and flow rate were also measured during the test and were observed to stay within Chromabolt® column specification (figure 8).

**Figure 8.** Protein bind and elute cycling study on Chromabolt® 10 cm Fractogel® EMD TMAE HiCap column.



### Cycle Performance of a 10 cm Chromabolt® column prepacked with Fractogel® EMD TMAE HiCap resin

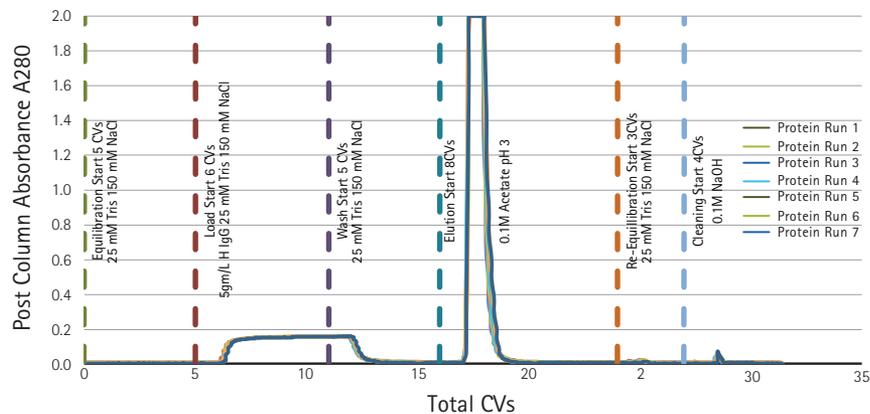
Cycles	Asymmetry	HETP	Flow
Fractogel® EMD TMAE HiCap resin in Chromabolt® specifications	0.7 - 1.8	≤ 0.1 cm	≥ 150 cm/hr
0	1.13	0.037	207
2	1.06	0.040	195
4	1.15	0.041	199

## Eshmuno® A Resin Study

A Chromabolt® 10 cm prepacked column containing Eshmuno® A resin was tested for 32 process cycles. Each cycle consisted of equilibration, loading, elution, and cleaning steps. Protein (human gamma globulin, hlgG) was loaded onto the column in every fifth cycle (Cycles 1, 6, 11, 16, 21, 26, 31). The remaining cycles consisted of buffer loading.

	Asymmetry	HETP (cm)	Flow at 15 psi (cm/h)
Initial column test	1.23	0.0216	313
Final column test (after 32 cycles)	1.41	0.0199	338

**Figure 9.** Protein bind and elute cycling study on Chromabolt® 10 cm Eshmuno® A column.



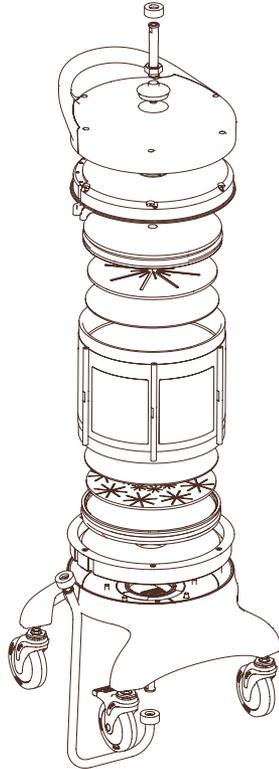
All 32 cycles were successfully performed. No issues were observed with bed integrity or the physical column integrity during the course of the study. The column asymmetry, HETP, and flow rate were measured before, during, and after the cycling study and were observed to

be within Chromabolt® Eshmuno® A column specifications in all cases. All HETP values were within the specification (≤0.1 cm). All asymmetry values were within specification (0.8-1.8). All flowrates were within the specification (≥200 cm/h at 15 psi).

## Ergonomics: Column Design

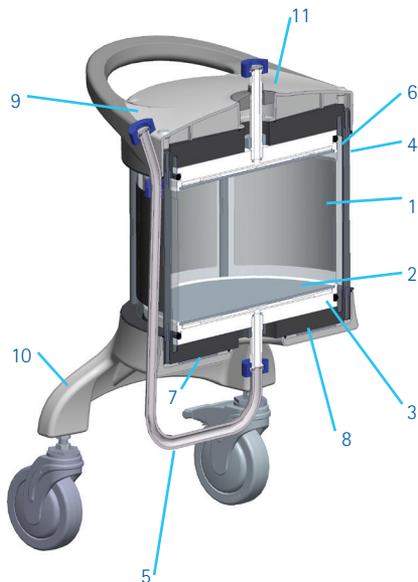
In addition to ensuring that the chromatography resin would maintain its performance characteristics in day-to-day operations, column engineering and design focused on making Chromabolt® columns

intuitive to use, simple to wipe and clean and easy for one person to transport.



Each piece of the Chromabolt® column has been designed to safely and robustly purify drug products.

## Materials of Construction



No.	Part	Material of construction
1	Tube	Acrylic
2	Frit	Polyethylene
3	Header/TC	Polypropylene
4	Hardware	Stainless steel
5	Flex Tube	Tygon® tubing
6	O-rings	EPDM
7	O-rings not in fluid path	Silicone
8	Endcaps	PVC
9	Hats and Handles	PBT
10	Shoe	Glass Filled Polypropylene
11	Flashing	Silicone

## Ordering Information

Chromabolt® Columns (All Sizes)	
Sizes (id) (rounded)	10, 20, 32 cm
Bed Height	20 cm fixed
Manufacturing Clean Room	ISO 8 Certified
Regulatory	Wetted parts are animal free or meet EMEA/410/1 requirements, and meet USP Class VI.
Pressure Ratings	3.5 bar (50 psig)
Shelf Life	Yes
Bioburden	≤ 100 CFU/mL
Endotoxin	≤ 1EU/mL
Shipping Test	ISTA-1E
HETP	Yes
Asymmetry	Yes

## Ordering Information

Name	Size (i.d.) cm	Catalog No.
Chromabolt® Prepacked Column - Eshmuno® S resin	10	CHRPC10781
	20	CHRPC10782
	32	CHRPC10783
Chromabolt® Prepacked Column - Fractogel® EMD TMAE HiCap (M) resin	10	CHRPC18811
	20	CHRPC18812
	32	CHRPC18813
Chromabolt® Prepacked Column - Fractogel® EMD SO <sub>3</sub> (M) resin	10	CHRPC18821
	20	CHRPC18822
	32	CHRPC18823
Chromabolt® Prepacked Column - Eshmuno® Q resin	10	CHRPC10791
	20	CHRPC10792
	32	CHRPC10793
Chromabolt® Prepacked Column - Fractogel® EMD COO (M) resin	10	CHRPC18861
	20	CHRPC18862
	32	CHRPC18863
Chromabolt® Prepacked Column - Fractogel® EMD SE Hicap (M) resin	10	CHRPC18941
	20	CHRPC18942
	32	CHRPC18943
Chromabolt® Prepacked Column - Fractogel® EMD TMAE (M) resin	10	CHRPC18891
	20	CHRPC18892
	32	CHRPC18893
Chromabolt® Prepacked Column - Fractogel® EMD DEAE (M) resin	10	CHRPC18831
	20	CHRPC18832
	32	CHRPC18833
Chromabolt® Prepacked Column - Eshmuno® A resin	10	CHRPC10891
	20	CHRPC10892
	32	CHRPC10893

If you are interested in 1 cm (i.d.) x 20 cm Chromabolt® prepacked columns for research purpose only, please contact your local sales representative.

## Additional Literature and Resources

The following will be provided with every prepacked column:

HETP and Asymmetry results, User Guide, Certificate of Quality and Analysis for the column, Certificates of Analysis for the resin, and a sample bottle with 50 mL of the ion exchange resin (20 and 32 cm i.d. columns only).

A sample bottle with 50 mL of Eshmuno® A resin is provided for all 3 column sizes.

## To place an order or receive technical assistance

In Europe, please call Customer Service:

France: 0825.045.645

Spain: 901.516.645 Option 1

Germany: 069.86798021

Italy: 848.845.645

United Kingdom: 0870.900.46.45

For other countries across Europe, please call:

+44 (0) 115 943 0840

Or visit: [www.merckmillipore.com/offices](http://www.merckmillipore.com/offices)

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