

ХРОМАТОГРАФИЧЕСКИЕ СРЕДЫ ESHMUNO CP-FT



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Eshmuno[®] CP-FT Resin

A cation exchange resin specifically developed for the flow-through removal of aggregates using frontal chromatography

Aggregates in monoclonal antibody (mAb) therapeutics pose a significant risk to patients by increasing the potential of an immunogenic response and reducing efficacy. In contrast to other mAb impurities, aggregates are not efficiently removed by protein A chromatography. They are particularly challenging to separate from the monomeric protein since they have very similar isoelectric points and hydrophobicities.

Eshmuno[®] CP-FT cation exchange (CEX) resin is specifically designed to provide efficient removal of mAb aggregates in the flow-through frontal chromatography mode of operation enabling loading capacities 10× higher than traditional bind/elute CEX chromatography. Eshmuno[®] CP-FT resin facilitates greater manufacturing flexibility and process intensification while reducing the overall cost for the downstream purification of mAbs.

Benefits

Increased performance

- Superior flow-through removal of mAb aggregates
- High product recoveries at high mass loadings

Reduced costs

- Significant reduction in resin and buffer volume
- Smaller manufacturing footprint (smaller columns, buffer tanks, etc.)

Intensified process

- Low salt process conditions eliminate the need for dilution before subsequent ion exchange steps
- Significant reduction in processing volumes improves virus filtration and ultrafiltration processing economics

Enhanced ease of use

- Rigid base bead enables higher flow rates and easier column packing



Enabling Flow-Through Efficiency

Eshmuno® CP-FT resin was developed for the efficient flow-through removal of aggregates under strong binding conditions (pH 4.0-5.5, 3-7 mS/cm) that favor frontal chromatography. Under these conditions, both the mAb monomer product and the mAb aggregates will initially bind to the Eshmuno® CP-FT resin. The resin has a novel CEX tentacle surface chemistry (Figure 1) that facilitates displacement of the bound monomer by the larger aggregates enabling efficient removal of aggregates using a frontal chromatography mechanism.

The example in Figure 2 demonstrates the efficient removal of aggregates from mAb feed containing a challenging level of aggregates (7%). The monomer breaks through the column much earlier than the aggregates. Thus, the monomer recovery exceeds 85% at 600 g/L while the percentage of aggregates in the flow-through pool does not reach 1% until after a loading of 1000 g/L.

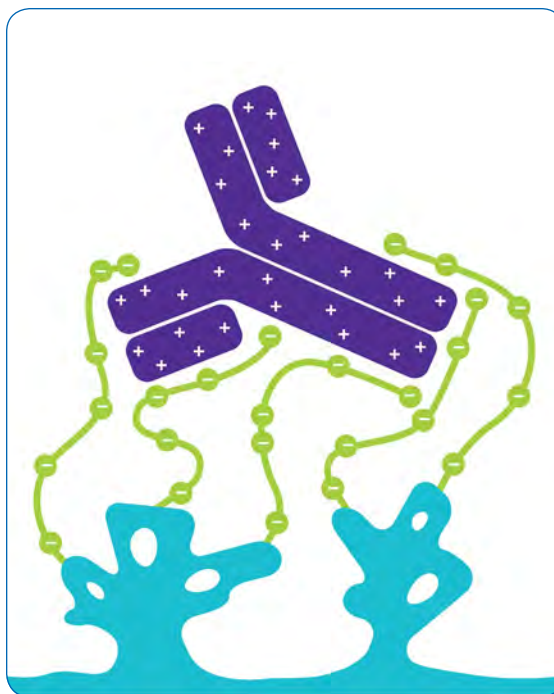


Figure 1.

Resin tentacles form a multipoint three-dimensional ion exchange network that enables easy access of the proteins to the ligands providing fast mass transport.

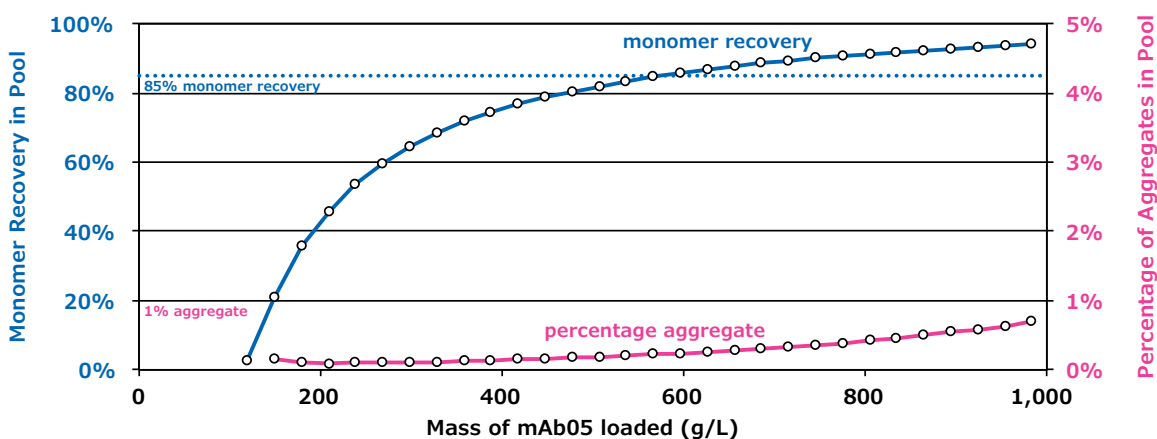


Figure 2.

Cumulative recovery of mAb05 monomer as a function of the mass of mAb05 loaded onto the column (blue—). Cumulative percentage of aggregates as a function of the mass of mAb05 loaded onto the column (pink—).

Using Eshmuno® CP-FT resin for high loading flow-through CEX chromatography offers significant savings over conventional CEX bind/elute chromatography processes. For instance, purifying 1 kg of a mAb using Eshmuno® CP-FT resin at a loading of 1,000 g/L would only require 1 L of resin and 15 L of buffer (Figure 3). This is significantly less than a CEX bind/elute chromatography process loaded to 80 g/L that would require 12.5 L of resin and 313 L of buffer.

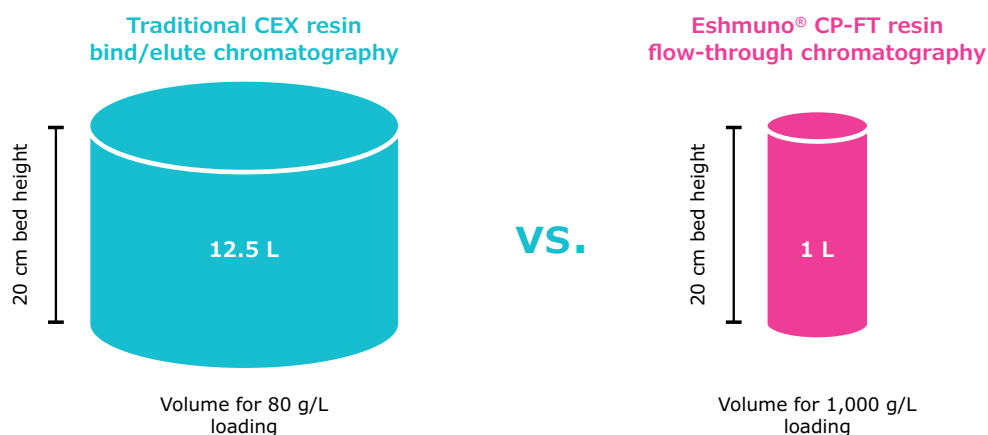


Figure 3.

Volume of columns to purify 1 kg of mAb.

Proven Eshmuno® Technology

Eshmuno® CP-FT resin is a member of our high performance Eshmuno® platform, which is a family of chromatography resins designed to meet the demands of highly productive downstream purification processes. Eshmuno® base beads (Figure 6) are composed of a hydrophilic polyvinyl ether polymer that enables high flow rates resulting in shorter processing times. Eshmuno® CP-FT resin can be easily packed into production-scale columns, either by simple flow packing or axial compression. The pressure-flow curves for 10 and 20 cm i.d. columns at 20 cm bed height are shown in Figure 7 demonstrating linear scalability.

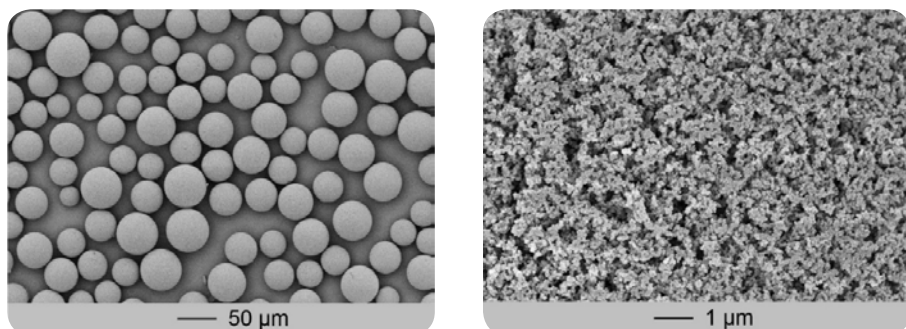


Figure 6.

SEM pictures of 50 µm particle size Eshmuno® CP-FT resin.

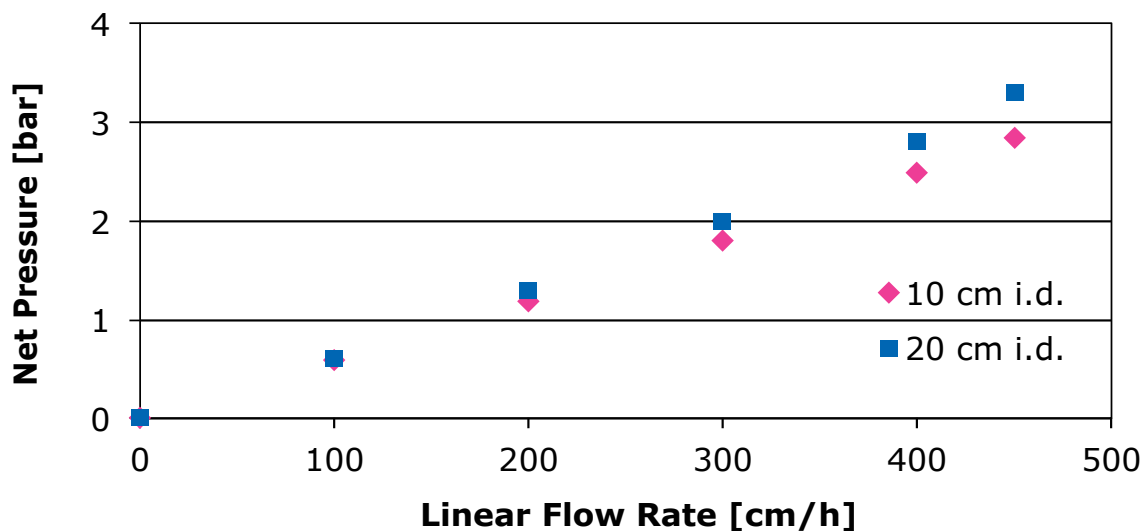


Figure 7.

Flow packed in 0.15 M NaCl, 20 cm bed height, 12% compression, running buffer: 0.15 M NaCl.

Ordering information

Description	Catalog Number
Eshmuno® CP-FT resin, 10 mL	1.20093.0010
Eshmuno® CP-FT resin, 100 mL	1.20093.0100
Eshmuno® CP-FT resin, 500 mL	1.20093.0500
Eshmuno® CP-FT resin, 5L	1.20093.5000
MiniChrom prepacked column with Column Eshmuno® CP-FT resin, 1mL 8x20mm	1.25168.0001
MiniChrom prepacked column with Column Eshmuno® CP-FT resin, 5mL 8x100mm	1.25169.0001
MiniChrom prepacked column with Column Eshmuno® CP-FT resin, 0.2mL 5x10mm	1.25170.0001
RoboColumn® prepacked column with Eshmuno® CP-FT resin, 0.2mL 8PC 5x10mm	1.25171.0001
RoboColumn® prepacked column with Eshmuno® CP-FT resin, 0.6mL 8PC 5x30mm	1.25172.0001

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