ХРОМАТОГРАФИЧЕСКИЕ СРЕДЫ ESHMUNO S/Q

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Eshmuno® S resin

For superior downstream mAB purification

Eshmuno® is a unique family of ion-exchange resins specifically designed for highly productive downstream bioprocess-ing. The cation exchanger Eshmuno® S is the first member of the Eshmuno® resin family and is highly productive in direct capture and post-protein A steps.

Benefits

- Superior productivity for mAB downstream processing
- More selectivity and HCP removal
- Active tentacle adsorption
- Robust and safe packing procedures
- Tangible savings in cost and development time

Eshmuno® S resin characteristics

Type	Strong cation exchanger
Functional group	$-SO_3$
Base matrix	Surface grafted rigid polyvinyl ether hydrophilic polymer
Lysozym capacity	115–165 mg/mL settled resin
Ionic capacity	50–100 µeq/mL settled resin
Mean particle size	75–95 µm
IgG dynamic capacity	>60 mg/mL (2 min. residence time)
Pressure drop (100 x 16 mm, 5 mL/min., 150 cm/h)	<1.0 bar

Superior productivity for mAB downstream processing

Eshmuno® S resin exhibits a superior binding capacity for antibodies compared to other modern cation-exchangers. Fig. 1 shows the dynamic binding capacity (DBC) for direct capture of a monoclonal antibody mAB02 at 5% breakthrough and 5 min. residence time from a real diluted feedstock. The DBC of Eshmuno® S resin is approximately 50% higher than the capacity of other surface-grafted cation exchangers.

A similar superior binding capacity can be shown in post-protein A purification steps. Fig. 2 illustrates the increased binding capacity of Eshmuno® S resin in an intermediate purification step of mAB03.

Pressure versus flow curve of Eshmuno® S resin

In combination with the excellent pressure flow behaviour (Fig. 3) an outstanding productivity of more than 40 mg/mL x h (dimension for productivity) for Eshmuno® S resin can be achieved, resulting in considerable manufacturing cost savings in mAB production.

Superior mAB binding capacity in direct capture step

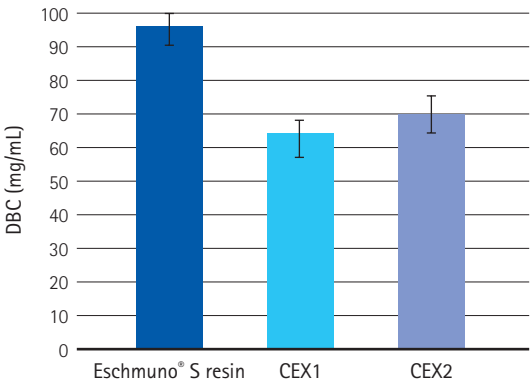

Figure 1.

mAB02 DC, 5% breakthrough, 4.3 mS/cm, pH 6.0 [mAB02] = 0.62 mg/mL, 5 min. residence time, 1 mL scout column

Binding capacity of purified mAB03 on Eshmuno® S resin

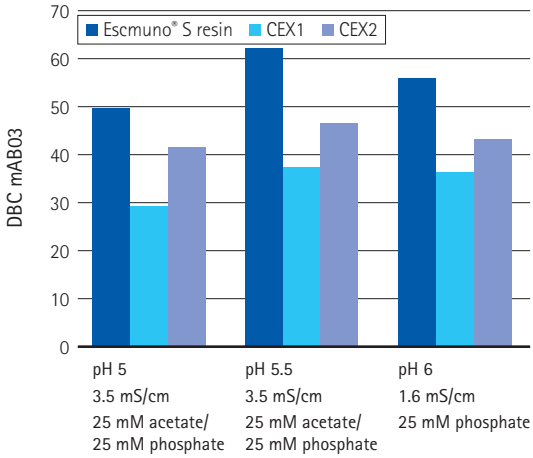

Figure 2.

DBC of mAB03 5 mg/mL in buffer A, 2 min. residence time, 1 mL scout column

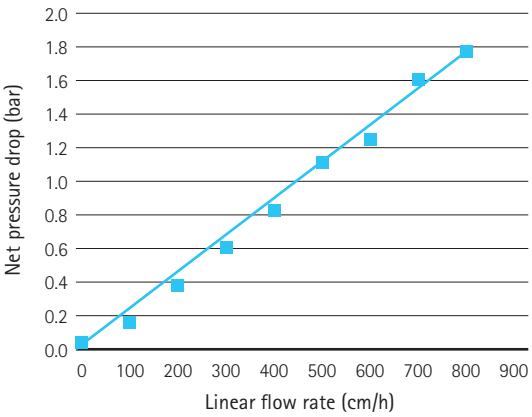

Figure 3.

20 cm i.d. column; 19,5 cm bed height; 8% compression recorded in 150 mM NaCl

More selectivity and HCP removal

A crucial property of any ion exchange material in biochromatography is the ability to specifically select the biomolecule of interest. While Eshmuno® S resin carries the same functional group like Fractogel® SO_3 resin, a slightly modified selectivity can be observed (Fig. 4), which allows a wider flexibility for the specific purification challenge.

The result: Eshmuno® S resin is the most efficient resin in the removal of host cell proteins (Fig. 5).

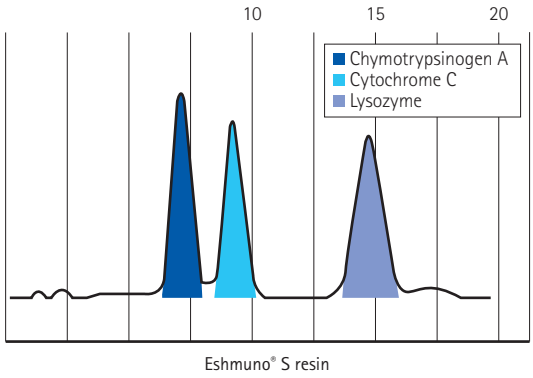

Figure 4.

A mixture of ■Chymotrypsinogen A, ■Cytochrome C, and ■Lysozyme was separated under standard conditions

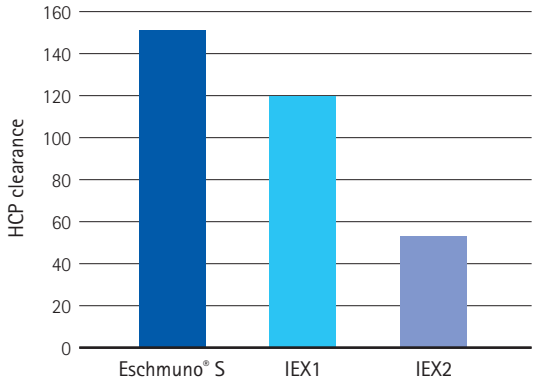

Figure 5.

HCP Clearance factor of mAB02, 5% breakthrough, 4.3 mS/cm, pH 6.0, 5 min. residence time, 1 mL scout column

Active tentacle technology

Merck KGaA was the first manufacturer of a biochromatography resin (Fractogel®) with tentacle structure (Fig. 6). The main advantage of this tentacle chemistry is the increased amount of sterically accessible ligands to more effectively bind the biomolecule of interest thus increasing the capacity of the resin.

Eshmuno® S resin combines both, the reliable tentacle technology with the properties of a new hydrophilic polyvinyl ether base matrix. The polymer matrix allows the use of much higher flow rates, while the biomolecule is still strongly bound by the tentacle.

Figure 6.

Resin tentacles forming a three-dimensional ion exchange network, enable easy access of the proteins to the ligands

Ordering Information

Description	Catalogue No.
Eshmuno® S resin	1.20078

Eshmuno® Q resin
For efficient AEX chromatography

Eshmuno® Q resin is a strong anion exchange resin, coupling our renowned tentacle structure with a hydrophilic polyvinyl ether base matrix. Consequently, Eshmuno® Q resin offers outstanding results in typical anion exchange applications such as removing biomolecules' impurities in flow-through mode, or separating blood factors in plasma processing.

Benefits

- Superior productivity for downstream processing of biomolecules
- High flow rate versus pressure flow behavior
- Excellent removal of impurities
- Robust and safe packing procedures
- Strong chemical stability

Table 1: Eshmuno® Q resin charateristics

	Eshmuno® Q Resin
Type of chromatography	Strong anion exchanger
Functional group	Trimethylammoniumethyl (TMAE)
Base material	Surface grafted rigid hydrophilic polyvinyl ether polymer
Mean particle size (d_{50})	85 µm
Dynamic protein binding capacity: 2 min. residence time, 10% breakthrough (BT)	≥ 96 mg BSA/mL packed resin ≥ 48 mg IgG/mL packed resin
Ionic capacity	90-190 µmol/mL, settled resin
pK value	≥ 13
pH stability during operations*	In working conditions (proteins/contaminants binding and elution): pH 2 to 12 In cleaning and sanitization: pH 0 to 14
Mechanical stability	8 bar
Linear flow rate	up to 1000 cm/h (2.5 bar net pressure) 20x10 cm i.d. column, 8% compression, 150 mM NaCl as mobile phase
Storage conditions**	20% EtOH/150 mM NaCl solution, at ambiant temperature
Shipping solution	20% EtOH/150 mM NaCl solution

* Recommended pH intervals where the resin can be operated, at room temperature, without significant change in function

** Time interval between utilizations of the resin

Eshmuno® Q resin exhibits a superior binding capacity for various biomolecules. Fig. 1 shows the dynamic binding capacity (DBC) of Eshmuno® Q resin for selected macromolecules at different flow rates:

High flow rates (2 min. residence time correspond to approximately 600 cm/h) do not significantly affect the high binding capacities obtained at lower flow rates.

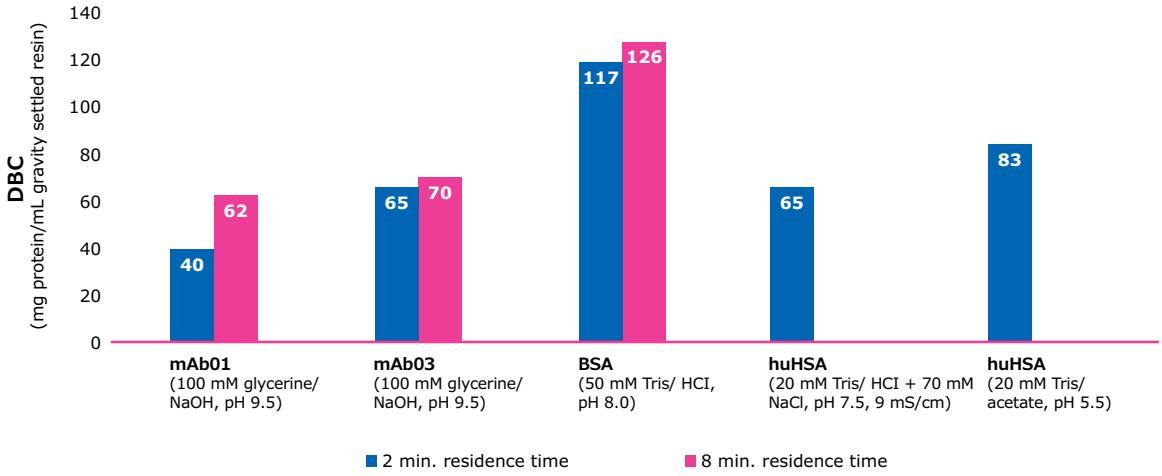

Figure 1.
Dynamic binding capacities (DBC) measured at 10% breakthrough

Applications

Monoclonal Antibody (mAbs) Impurities Removal

Table 2: Feed Material Information

Feed Description (process stage)	Concentration (g/L)	Conductivity (mS/cm)	Protein A (ppm)	HCP (ppm)
Post protein A pool mAb05	2.9	5	11	1448
Post protein A pool mAb08	5.1	5	237	4392

Device: 1 mL column (8 mm x 20 mm) prepacked with Eshmuno® Q resin
Equilibration conditions: Buffer 25 mM tris, pH 7.5 at 5 mS/cm

HCP removal

Table 3 shows the percentage of HCP removal using Eshmuno® Q resin at an intermediate loading point of 153 g/L and at the target loading of 250 g/L.

Table 3: HCP % removal

	mAb08 - 153 g/L	mAb08 - 250 g/L	mAb05 - 153 g/L	mAb05 - 250 g/L
Eshmuno® Q resin	77%	82%	80%	73%

Leached Protein A removal

Table 4 shows the percentage of leached Protein A removal using Eshmuno® Q resin at an intermediate loading point of 153 g/L and at the target loading of 250 g/L.

Table 4: Leached Protein A % removal

	mAb08 - 153 g/L	mAb08 - 250 g/L	mAb05 - 153 g/L	mAb05 - 250 g/L
Eshmuno® Q resin	97%	96%	55%	20%

Ordering information

Eshmuno® Q Resins

Product Description	Catalogue No.
Eshmuno® Q resin	1.20079
Eshmuno® Q bulk media	
10 mL	1.20079.0010
100 mL	1.20079.0100
500 mL	1.20079.0500
5000 mL	1.20079.5000
Eshmuno® Q resin in prepacked columns	
MiniChrom Column	
1 mL	1.25065.0001
5 mL	1.25074.0001
RoboColumn®	
0.2 mL	1.25133.0001
0.6 mL	1.25141.0001
Chromabolt® Columns	
10 cm	CHRPC10791
20 cm	CHRPC10792
32 cm	CHRPC10793

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