Discover the smart side of process economics

Eshmuno™ – The smart resin

MERCK

Passion for performance

for your biopharma process

The biopharmaceutical production has matured. Today the main focus of any biopharmaceutical production platform is put on safety and efficiency. We at Merck KGaA concentrate our R&D for the biopharmaceutical industry on these two key elements.

As a biopharmaceutical manufacturer you profit from Merck in multiple ways as we offer not only resins for downstream processing but in addition a variety of chemicals and enzymes for challenges in Upstream, Downstream and Formulation.

Eshmuno™ is a new and unique ion-exchange resin specifically designed for highly productive downstream purification of monoclonal antibodies; The cation exchanger Eshmuno™ S is the first product of the Eshmuno™ family of smart resins and is highly productive in direct capture and post-protein A steps.

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

Type	strong cation exchanger
Functional group	- SO_3
Base matrix	Surface grafted rigid poly vinyl 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 (100x16mm, 5ml/min, 150 cm/h))	< 1.0 bar

Superior mAB binding capacity in direct capture step

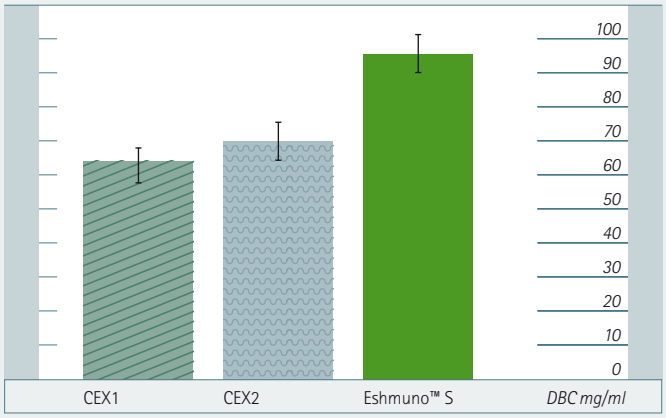

fig. 1: mAB02 DBC , 5% breakthrough, 4.3 mS/cm, pH 6.0 [mAB02] = 0.62 mg/ml, 5 min residence time, 1 ml Scout

Binding Capacity of purified mAB03 on Eshmuno™ S

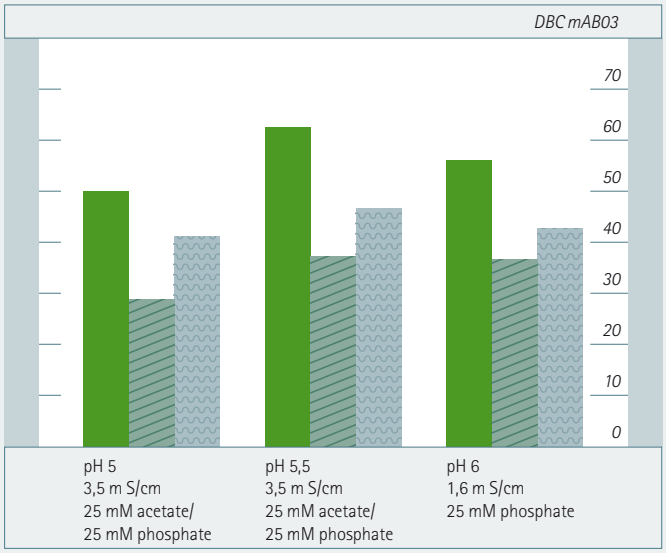

fig. 2: DBC of mAB03 5mg/ml in buffer A, residence time 2 min, 1 ml scout column
Eshmuno™ S CEX1 CEX2

Superior productivity for mAB downstream processing

Safety and efficiency are the key elements of any purification scheme for biological molecules. Downstream processing is the most time consuming and most costly process step in the manufacture of biological drugs. Particular care has to be taken into account when selecting the raw materials which come in direct contact of the biological active ingredient.

Eshmuno™ S 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 minutes residence time from a real diluted feedstock. The DBC of Eshmuno™ S is approximately 50% higher than the capacity of other surface-grafted cation exchangers.

A similar superior binding capacity can be shown in post-protA purification steps. *fig. 2* illustrates the increased binding capacity of Eshmuno™ S in an intermediate purification step of purification of mAB03.

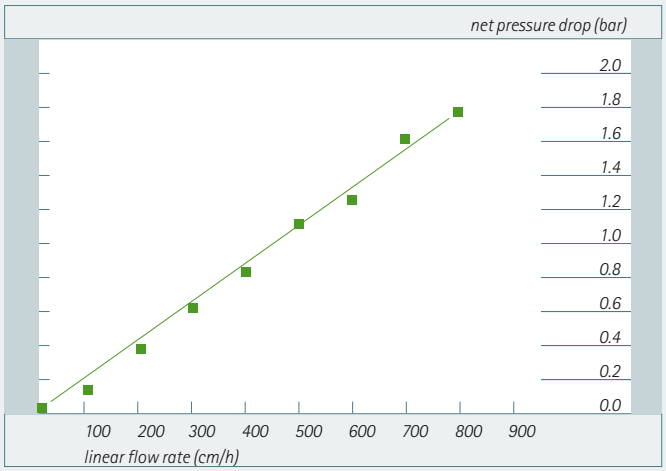

fig. 3: 20 cm i.d. column; 19,5 cm bed heigh; 8 % compression recorded in 150 mM NaCl

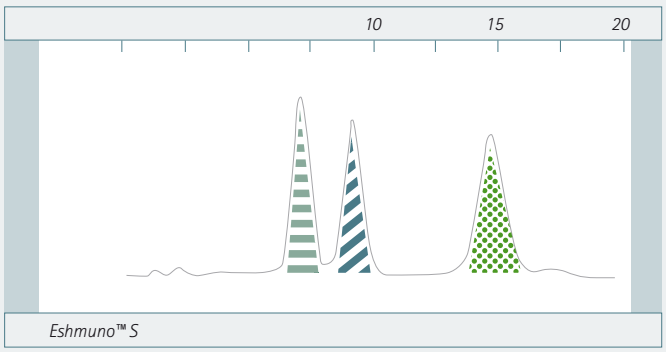

fig. 4: A mixture of chymotrypsinogen A, cytochrome C, and lysozyme was separated under standard conditions.

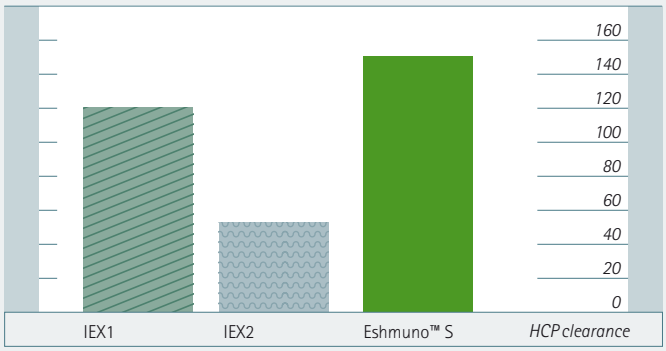

fig. 5: HCP Clearance factor of mAB02, 5% breakthrough, 4.3 mS/cm, pH 6.0, 5 minutes residence time, 1 ml Scout column

Pressure versus flow curve of Eshmuno™ S

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 can be achieved, resulting in considerable manufacturing cost savings in mAB production.

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 carries the same functional group like Fractogel SO_3 a slightly modified selectivity can be observed *(fig. 4)*, which allows a wider flexibility for the specific purification challenge.

The consequence: Eshmuno™ S is the most efficient resin in the removal of the host cell proteins *(fig. 5)*.

Active tentacle technology

Merck KGaA was decades ago 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™ 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.

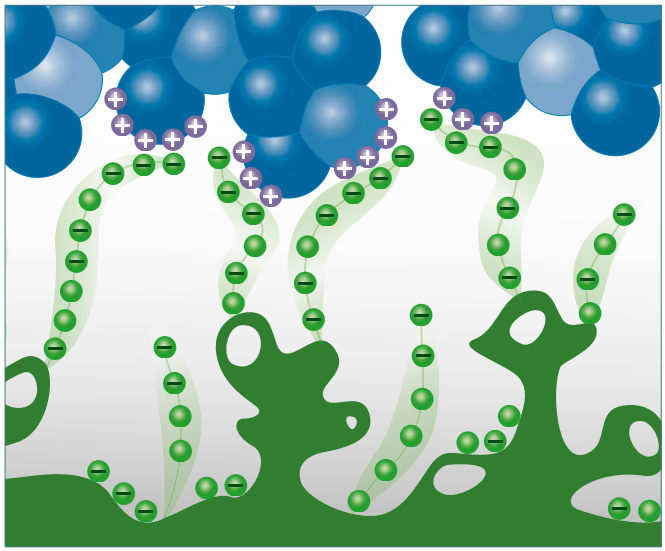

fig. 6: Active tentacle technolygy

Robust and safe packing procedures

Eshmuno™ S can be easily packed into production scale columns for biochromatography either by simple flow packing or axial compression. To prevent corrosion of the tubing system, Eshmuno™ columns can be packed using 0.01 M sodium hydroxide solutions and even pure water resulting in plate numbers > 2400/m with good peak symmetry. Packing procedures and cleaning protocols can be easily obtained from: **www.merck4pharma.com** or **processing@merck.de**

For the packing of Eshmuno™ and sanitization of the column we recommend Merck chemicals especially dedicated for the use in biopharmaceutical production with the brandname EMPROVE® bio.

480910 Ethanol 20% suitable for the biopharmaceutical production and for cleaning and storage of chromatography resins
137020 Sodium hydroxide pellets suitable for the biopharmaceutical production Ph Eur,BP,JP,NF,ACS
106482 Sodium hydroxide pellets extra pure Ph Eur,BP,JP,NF,FCC,E 524
137031 Sodium hydroxide solution 1 mol / l suitable for the biopharmaceutical production
137040 2-Propanol 70% suitable for the biopharmaceutical production
104219 Guanidinium chloride for biochemistry
137030 Urea cryst. suitable for the biopharmaceutical production EMPROVE® bio Ph Eur,BP,JP,USP,ACS

Tangible savings in cost and development time

With the use of Eshmuno™ in downstream processing considerable manufacturing cost savings can be achieved. The productivity of purification in a model process of a monoclonal antibody could be increased 5 fold by using Eshmuno™ S instead of a convential soft-gel ion exchanger. The use of Eshmuno™ S instead of a protein A based capture step can save up to 30% of your purification costs.

Order information: 1.20078 Eshmuno™ S

Our Global Applied Technology Department supports Eshmuno™ users with a global network of application centers on three continents and with renowned training programs.

Check our latest courses here:
http://www.merck4pharma.com/workshops

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