ХРОМАТОГРАФИЧЕСКИЕ СРЕДЫ ESHMUNO A/P

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Eshmuno® A Chromatography Media

Introduction

Eshmuno® A is a rigid, high capacity, acid and alkaline resistant Protein A affinity chromatography media for the purification of Fc-containing proteins, including but not limited to monoclonal antibodies.

It exhibits the following key advantages relative to competitive products.

- Acid resistance
- Alkaline resistance
- Aggregate removal

Eshmuno® A media can be cleaned and sanitized under acid and/or alkaline conditions while maintaining high dynamic binding capacity at high flow rates. In addition, it offers an orthogonal solution for aggregate removal at both the front and tail ends of the elution peak from the Protein A column. This property of the Eshmuno® A media results in reducing the burden of subsequent chromatography steps typically used in the purification of Fc–containing proteins.

Proven Technology

The Eshmuno® A media contains a Merck Millipore proprietary ligand derived from the C domain of *Staphylococcus aureus* Protein A in a pentameric form. This ligand is recombinantly expressed in *E. coli*. No animal derived products are used during production.

The Eshmuno® A media is synthesized via immobilization of the aforementioned ligand on to the Eshmuno® base matrix, which is a rigid and hydrophilic polymer based on polyvinylether.

Additional Advantages of Eshmuno® A Media

Productivity

- High Binding Capacity
- Superior Flow Capability
- Reusability
- Low Cost of Goods (COGs)

Product Purity

- Increased Aggregate Removal
- Excellent HCP Reduction
- Low Leached Protein A
- Consistent Viral Clearance
- Reduced Fab Binding

Scalability

- Linear Scale Up

Reliability

- Batch to Batch Consistency
- GMP Manufacturing Environment
- Continuous Regulatory Support

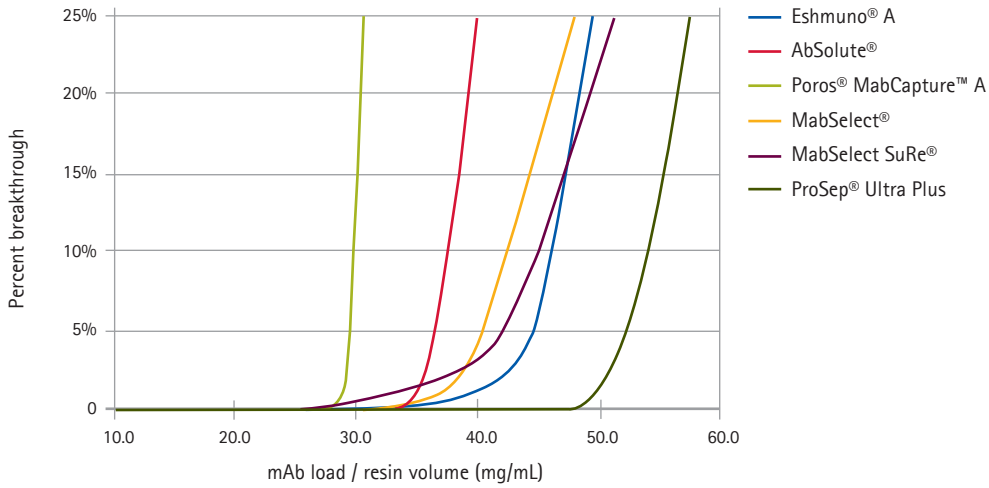
High Binding Capacity

Optimizing the particle and pore size of the Eshmuno® base matrix along with the immobilization of the Merck Millipore proprietary ligand enables a significant increase in dynamic binding capacity.

The breakthrough curves of various commercially available Protein A media at 3 minutes residence time are depicted in figure 1. As demonstrated in figure 1, the Eshmuno® A media shows higher dynamic binding capacity than other competitive affinity media.

As a result of the optimized particle and pore size of the Eshmuno® base matrix, the sharp breakthrough curve observed in figure 1 allows for higher loading of Fc-containing protein to be purified, thereby maximizing column throughput.

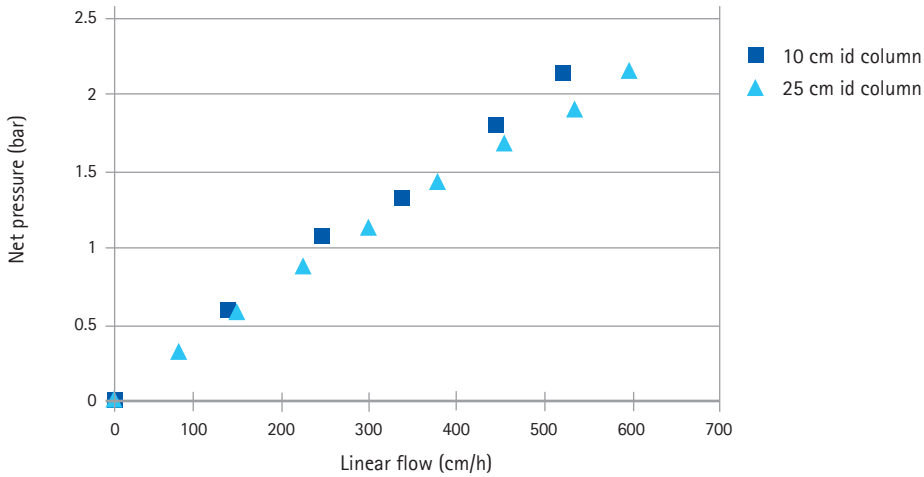
Figure 1. Breakthrough Curve at 3 min Residence Time



Operational Flexibility

The intrinsic rigidity of Eshmuno® A base matrix ensures a linear relationship between back pressure and flow rates throughout the standard range of operating conditions.

Figure 2. Pressure versus Flow Curves



Media characteristics overview

Type	affinity media
Base material (or matrix)	hydrophilic polyvinylether
Functional group	rec. Protein A produced in *E. coli*, derived from C domain of native Protein A
Mean particle diameter	~ 50 µm
Dynamic binding capacity	40 -55 mg/mL at 3-6 min RT and 5% breakthrough for mAbs.
Cleaning pH stability	1.5 – 13.5
Operating pH range	2.5 – 8.0
Mechanical stability	8 bar >500 cm/hr (20 cm bed height at 2 bar)
Linear flow rate	
Shipping solution	20% Ethanol, 150 mM NaCl

Ordering Information

Product	Order No.	Size
Eshmuno® A media	1.20089.0010	10 mL
	1.20089.0100	100 mL
	1.20089.0500	500 mL
	1.20089.5000	5 L
	1.20089.9010	10 L
MiniChrom™ Column	1.25160.0001	1 mL
	1.25161.0001	5 mL
RoboColumn®	1.25162.0001	0.2 mL
	1.25163.0001	0.6 mL

Eshmuno® P Chromatography Resins

High performance, acid and alkaline resistant affinity chromatography resins designed for the removal of anti-A and anti-B antibodies from plasma-derived immunoglobulin (Ig).

Trace amounts of anti-A and anti-B isoagglutinins in plasma- derived immunoglobulin (Ig) have been associated with increased patient risk for hemolysis, a serious and sometimes fatal complication.

Eshmuno® P anti-A and Eshmuno® P anti-B are two distinct affinity based chromatography resins specifically designed to effectively remove anti-A and anti-B isoagglutinins, respectively.

Key Advantages:

- Reduced patient risks
- Improved economics
- Operational flexibility
- Improved quality control

Proven Technology

Eshmuno® P resins leverage the proven technology of the highly stable Eshmuno® base matrix coupled with target specific ligands. Eshmuno® P resins are synthesized via immobilization of trisaccharide blood group antigens (A & B) on to the Eshmuno® base matrix, which is a rigid and hydrophilic polymer based on polyvinylether.

Reduced Patient Risk

Eshmuno® P resins help reduce the risk of hemolytic reactions by reducing the levels of anti-A and anti-B isoagglutinins in the final product.

Both resins show excellent anti-A and anti-B removal capacity: Greater than 75% of anti-A and anti-B removed between pH 5 through pH 9. Refer to figure 1 below.

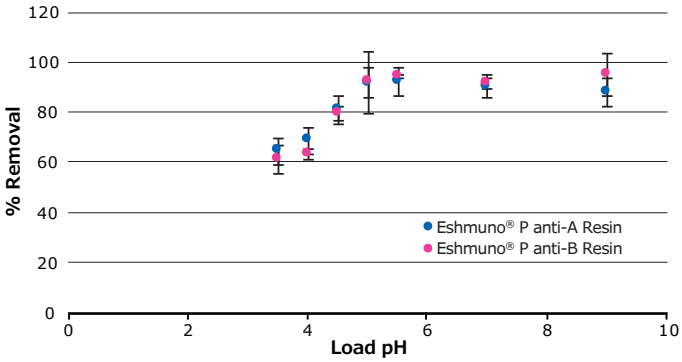


Figure 1

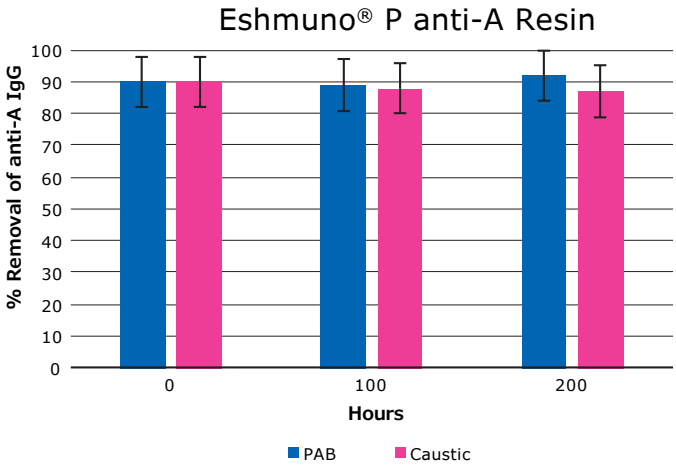
anti-A and anti-B % removal

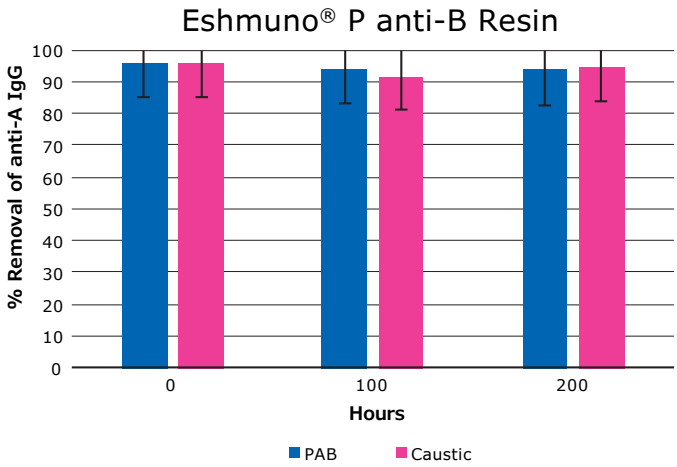
Improved Economics

The ability to reuse chromatography resins is important for designing cost effective purification processes. Such reuse is enabled by stability of the media in routine cleaning solutions. Eshmuno® P resins can be used for multiple cycles employing acid or alkaline cleaning without loss of performance.

Studies for reuse after cleaning-in-place (CIP) were simulated by exposing the Eshmuno® P resins to two common CIP solutions for 200 hours. The solutions were 0.5 M NaOH and a solution of 120 mM phosphoric acid, 167 mM acetic acid and 2.2% benzyl alcohol, which is typically referred to as PAB. The stability of the resins and therefore, the ability to reuse was confirmed by testing the anti-A and anti-B removal capacity of the resins before and after the exposure to the CIP solutions.

The results of these studies are shown in figures 2 and 3 below. Both Eshmuno® P resins show minimal to no reduction in the removal capacity up to 200 hours of exposure to 0.5 M NaOH and PAB solutions enabling reuse for multiple cycles depending upon the cycle definition.



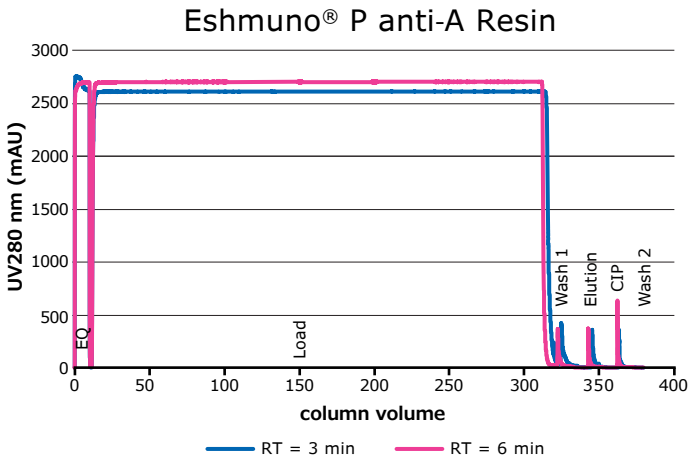


Figures 2 and 3

Alkaline and acid resistance for Eshmuno® P Anti-A and Anti-B media.

Operational Flexibility

Eshmuno® P resins show excellent removal of anti-A and anti-B issoagglutinins with high product yields irrespective of flow rates. This translates into high productivity with operational flexibility for Eshmuno® P resins. Figures 4 and 5, and table 1 illustrate these benefits.



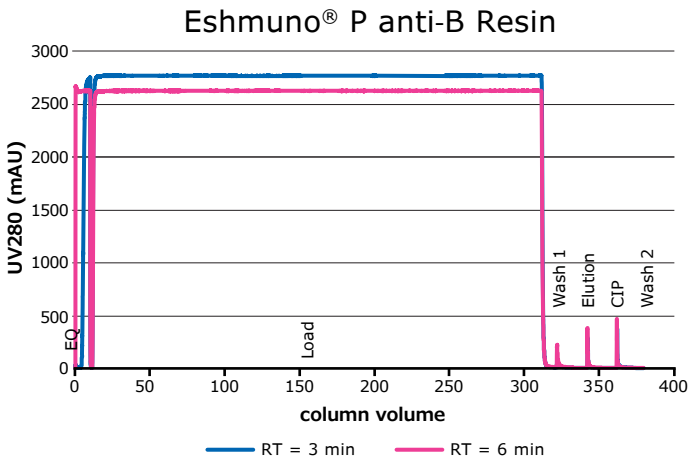


Figure 4 and 5

Chromatograms for Eshmuno® P anti-A and anti-B at 3 and 6 minute residence times

Resin	3 min residence time		6 min residence time	
	Removal (%)	Yield (%)	Removal (%)	Yield (%)
Eshmuno® P anti-A resin	93	96	90	97
Eshmuno® P anti-B resin	94	97	93	99

Table 1

% anti-A/B Removal and % Yields in Flow-through at IgG load of 3 kg/L and pH = 5.5

The intrinsic rigidity of Eshmuno® P base matrix ensures a linear relationship between back pressure and flow rates throughout the standard range of operating conditions. Figure 6 below shows the pressure versus flow curves for a column of 20 cm id × 20 cm height at the compression factors of 1.11 and 1.14. The recommended range of compression factor is 1.11 to 1.17.

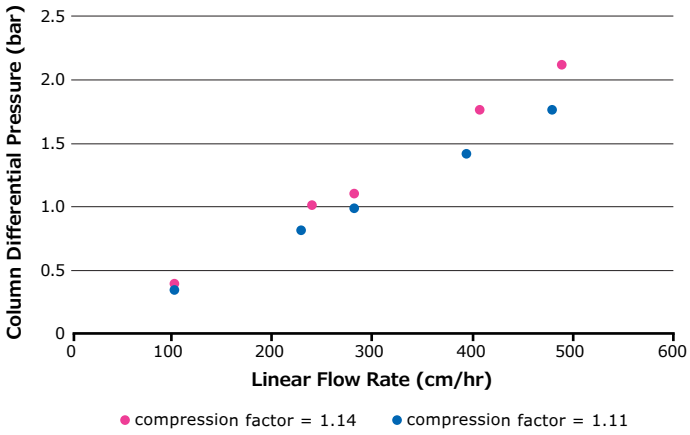


Figure 6

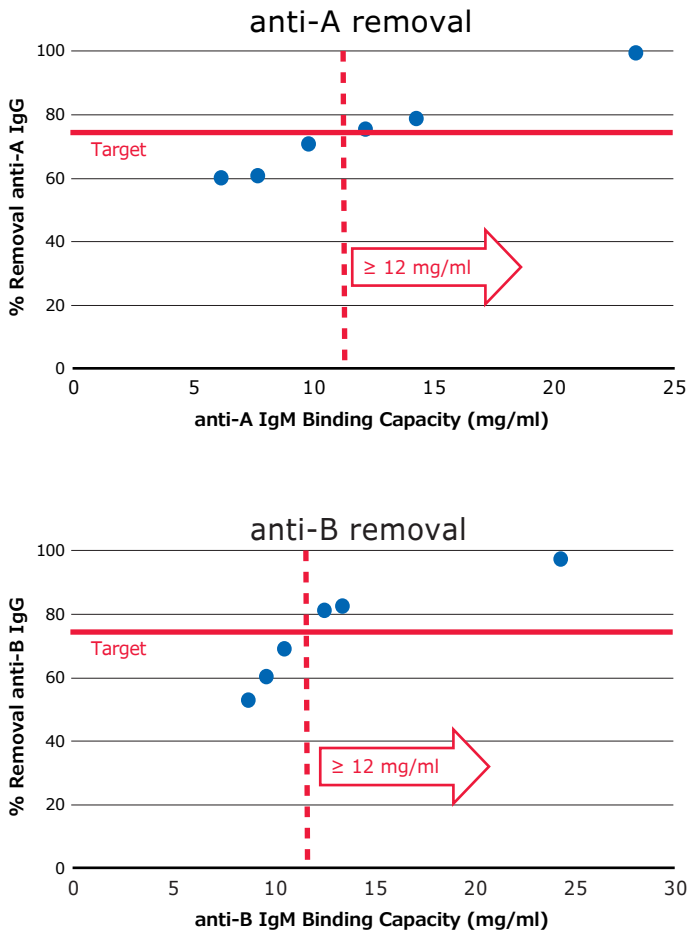
Pressure versus Flow Curves

Improved Quality Control

The classical agglutination assays used to measure anti-A and anti-B levels are known to be highly variable due to the nature of the test and the test samples. To avoid the inconsistency of conventional assays, we developed an innovative assay to test for the resin performance.

This novel assay is used for the routine quality control testing of Eshmuno® P resins. The assay is highly simplified, and involves measuring the depletion of the IgM after incubation with respective Eshmuno® P resins using UV spectroscopy. The applicability of this method is confirmed by establishing a correlation between IgM binding capacity and ability to remove anti-A or anti-B Ig.

A linear relationship is observed between the resin's anti-A and anti-B IgM binding capacity and the ability to remove anti-A and anti-B IgG, respectively. Resins with IgM binding capacity of ≥ 12 mg/ml show higher than 75% removal in case of both anti-A and anti-B IgG. This is shown in figures 7 and 8 below.



Figures 7 and 8

anti-A and anti-B IgM Binding Capacity Correlation to % Removal.

Media characteristics overview

Type	Affinity media
Base material (or matrix)	Hydrophilic polyvinylether
Functional group	Trisaccharide blood group antigens (A or B)
Mean particle diameter	~ 50 µm
Cleaning pH stability	1.5 – 13.5
Operating pH range	2.0 – 9.0
Mechanical stability	8 bar
Linear flow rate	> 500 cm/hr (20 cm bed height at 2 bar)
Shipping solution	20% ethanol

Ordering Information

Product	Size	Order No.
Eshmuno® P anti-A	10 mL	1.20094.0010
	100 mL	1.20094.0100
	500 mL	1.20094.0500
	5 L	1.20094.5000
Eshmuno® P anti-B	10 mL	1.20095.0010
	100 mL	1.20095.0100
	500 mL	1.20095.0500
	5 L	1.20095.5000

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