NEW from Natrix Separations

Introducing the Natrix HD-Sb Hydrogel Membrane

Cation Exchanger augmented with HIC Groups for Purification of Monoclonal Antibodies

- Extremely fast Capture or Polishing
- Very high dynamic binding capacity, excellent monomer recovery and high aggregate clearance
- High salt tolerance for robust processes

Explore the future of disposable downstream processing!

The new Recon HD-Sb membrane device is now available for lab scale exploration and DOE work. Low pressure Recon devices, ready-to-use with Luer lock fittings, are compatible with all benchtop chromatography systems. Larger devices for process development and clinical manufacturing are currently under development.

High Binding Capacity and high speed polishing with proven Natrix HD hydrogel technology

The high ligand density and excellent mass transfer of the three-dimensional macroporous hydrogel give a binding capacity >90 mg mAb/ml of membrane (10% breakthrough) at flow rates of 10 MV/min or greater (residence time of 6 seconds or less). In flowthrough mode, a single 0.8 ml Recon device can polish 250 mg of monoclonal antibody in one step.

High Aggregate Clearance and HCP Removal by mixed-mode chemistries

The HD-Sb membrane is a mixture of strong cation exchange (sulfonic acid) and hydrophobic (t-butyl) groups. This unique chemistry achieves highly purified antibodies in both bind & elute and flowthrough modes.

LEARN MORE: For more information, please visit: **www.natrixseparations.com/Sb**

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Natrix HD-Sb Hydrogel Membrane Columns: Performance Data

Figure A: From 8.1% aggregate to undetectable in bind/elute

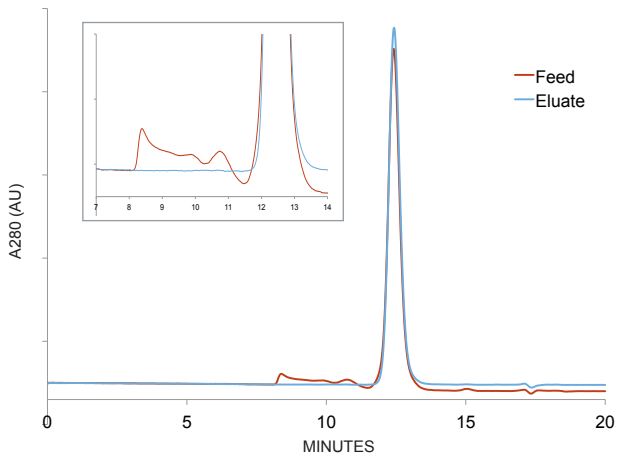
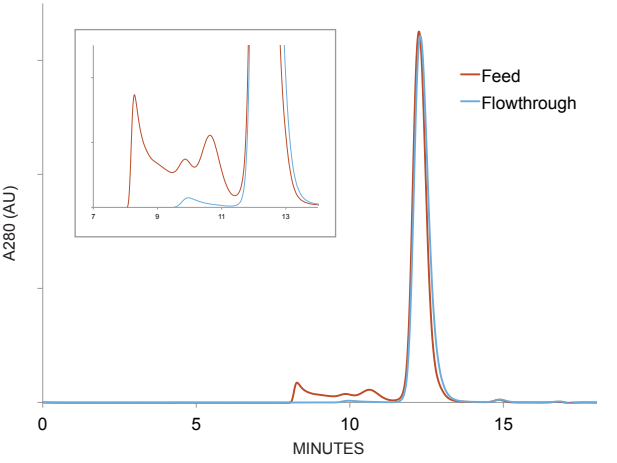


Figure B: From 12.8% aggregate to 0.6% in flowthrough



Figures A & B: High Aggregate Removal in Bind & Elute and Flowthrough Mode

SEC analyses of Feed and Eluate from Bind & Elute [Figure A] and Feed and Flowthrough [Figure B] experiments show highly efficient removal of aggregates. Load (50 mg/mL [A], 300 mg/mL [B]), flow rate 10 membrane volumes/minute, sample concentration (1 g/L [A], 3 g/L [B]) in equilibration buffer (45 mM Na-acetate, 130 mM NaCl, pH4.5 [A] pH5 [B], 16.3 mS/cm [A] 10 mS/cm [B]). Elution with wash buffer (20 mM phosphate, pH6.3) at 6 mS/cm.

Table 1: High Monomer yield in Bind & Elute and Flowthrough modes

The table below shows the exceptional clearance of aggregates and high monomer yield in both Bind & Elute and Flowthrough mode when used for polishing antibodies purified using Protein A chromatography.

Mode	Load	Aggregates		Monomer Yield
		Feed	Elution	
Bind & Elute	50 mg/mL	1.8%	Undetectable	>90%
Bind & Elute	50 mg/mL	3.3%	Undetectable	>90%
Bind & Elute	50 mg/mL	8.1%	Undetectable	>90%
		Feed	Flowthrough	
Flowthrough	300 mg/mL	12.8%	0.6%	>90%

Same antibody used in all experiments. Different Aggregates levels created by changing the time of the low ph holding step.

Table 2: High HCP and aggregate reduction in capture and intermediate applications.

The HD-Sb is capable of high impurities clearance for purification of monoclonal antibodies. Two different monoclonal antibodies were used for capture studies and for bind & elute studies after a ProA affinity purification step. The HD-Sb shows good clearance for HCP and aggregates in both cases.

Mode	Capture	Intermediate (B/E)
Load (mg/mL)	55	65
Flow rate (MV/min)	10	
HCP Clearance (LRV)	1.4	1.7
Load (ppm)	350,800	140
Eluate (ppm)	12,730	2.8
Aggregate Clearance		
Load	Not measured	1.80%
Eluate	2.60%	Not detectable
mAb Yield	> 90%	> 90%

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