CHROMATOGRAPHY MEDIA

Cellufine

Removal of Antibody Aggregates using

Cellufine MAX GS

Purification of therapeutic MAbs requires more advanced and selective means for separating aggregates from the target monomers. The new Cellufine MAX GS chromatography media is optimized for higher capacity, better separation and greater selectivity to improve downstream purification of MAbs. JNC Corporation's new strong cation exchanger, Cellufine MAX GS, has optimized ligand density for improved dynamic binding capacity and selectivity and superior pressure flow characteristics which are required by MAb purification platforms.

MAb monomer/aggregates Separation

Cellufine MAX GS exhibits exceptional selectivity between MAb monomers and their aggregates. Figure 1 and Table 1 show monomer/aggregates separation of purified mouse IgG subclass 1 from mouse ascites (MAb1) under NaCl stepwise elution. MAb 1 was treated with 1 M HCl (pH 2.5, 30 min) to generate aggregates. This solution, with a composition as described in Table 1, was used for high loading studies (75 mg-monomer/ml_resin). Cellufine MAX GS achieved excellent separation and recovery as confirmed by size exclusion chromatography.

Dynamic Binding Capacities

Efficient mass-transfer characteristics of Cellufine MAX GS translate to superior dynamic binding capacities (DBC). Figure 2 displays DBC for MAb1 and hPAb (human polyclonal antibody), which offer a performance advantages in both capture and polishing steps. Cellufine MAX GS may be operated suitably at residence times of 4-8minutes in antibody purification.

Other Characteristics of Cellufine MAX GS

Cellulose is a well-known natural product with high chemical and physical stability and Cellufine MAX employs a highly cross-linked cellulose as the base bead.. Thus, Cellufine MAX GS is operable at high velocities. All Cellufine IEX media can be cleaned and regenerated with 0.5 M NaOH solutions. Cellufine MAX GS is suitable for use in down-stream MAb purification platform. For more information on Cellufine MAX GS and other Cellufine products, please consult the JNC Corporation Cellufine website.

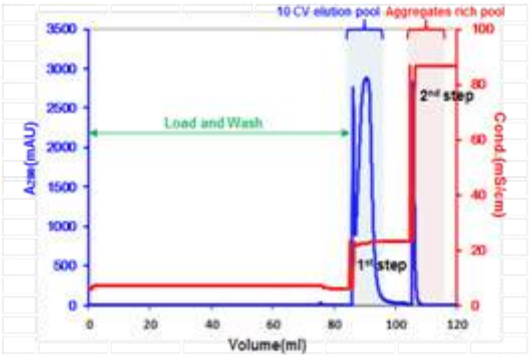

Figure 1. Separation of aggregates by stepwise elution
MAb Load: 75 mg/ml resin
Column: 5 mm ID × 5 cm L ,
A buffer: 10 mM Na-Acetate pH 4.5 + 50 mM NaCl
B buffer: 10 mM Na-Acetate pH 4.5 + 1 M NaCl
Load and wash: 0 % B,
1st step :18.5 % B, 2nd step:100 % B
Flow: 0.17 ml/min (load) , 0.50 ml/min (elution)
Sample: HCl treated mouse MAb1 (monomer: 92.6 %, dimer: 4.5 %, aggregates: 2.9 %)

	mg		
	Monomer	Dimer	Aggregates (> Dimer)
Total Feed	75.2	3.7	2.4
10 CV Elution pool	70.3	0.5	0.0
Aggregate Rich Pool	2.3	2.8	2.7

Table 1. MAb1 recovery and reduction of the dimer and aggregates
Recovery: 93.5 %
Purity: 99.3 % (in 10 CV elution pool)

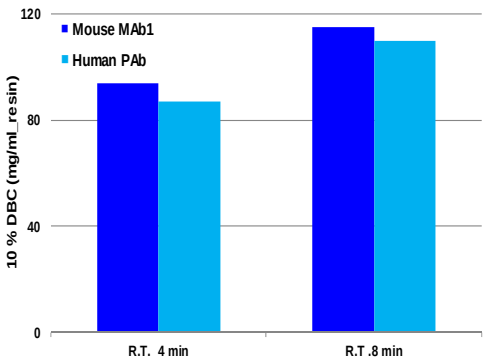

Figure 2. DBC of Cellufine MAX GS for the antibodies
Column: 5 mm ID × 5 cm L ,
Loading Buffer:
Mouse MAb1: 10 mM Na-Acetate pH 4.5 + 50 mM NaCl
Human PAb: 10 mM Na-Acetate pH 5.0 + 50 mM NaCl

JNC CORPORATION

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