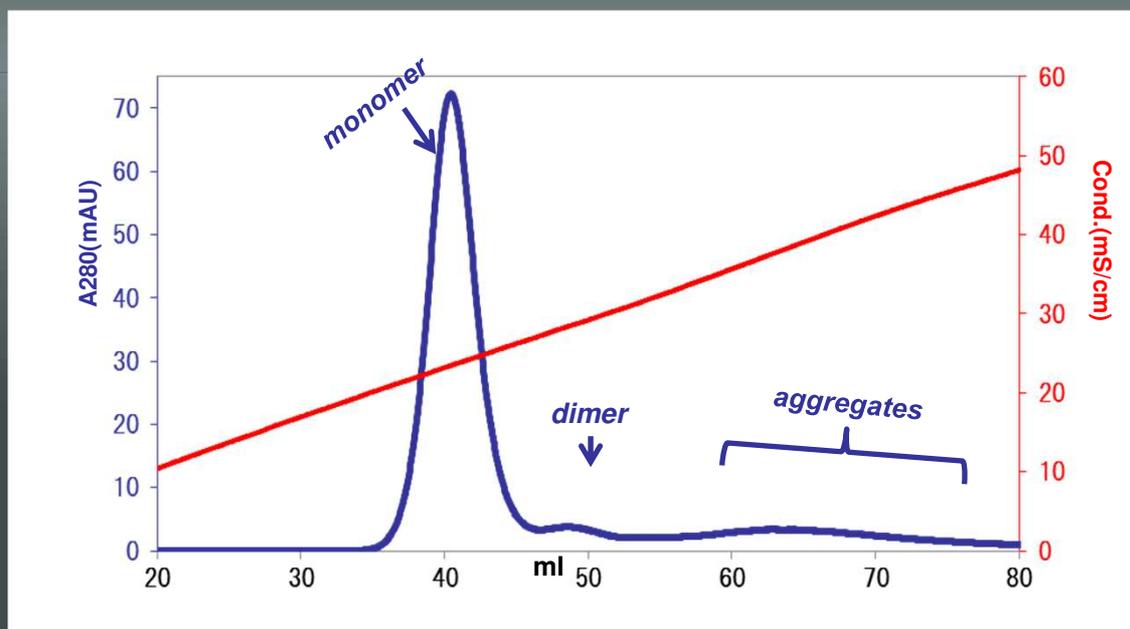


Cellufine™ MAX GS

IEX Chromatography media for MAb Downstream Processing



Cellufine MAX is the new generation Cellufine chromatography media. with high flow characteristics. Cellufine MAX GS is a strong cation ion exchange chromatography medium developed on the basis of a graft polymerization technique.

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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

Cellufine MAX GS is operable at high velocities. All Cellufine IEX media can be cleaned and regenerated with 0.5 M NaOH solutions. For more information on Cellufine MAX GS and other Cellufine products, please consult the JNC Corporation Cellufine website.

Description	Quantity	Catalogue No.
Cellufine MAX GS	5 x 1 mL cartridges	21 300-51
	5 x 5 ml cartridge	21 300-55
	100 mL	21 300
	500 mL	21 301
	5 L	21 302
	10 L	21 303

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www.jnc-corp.co.jp/fine/en/cellufine

Purchase/ technical Support

e-mail: cellufine@jncamericany.com or cellufine@jnc-corp.co.jp

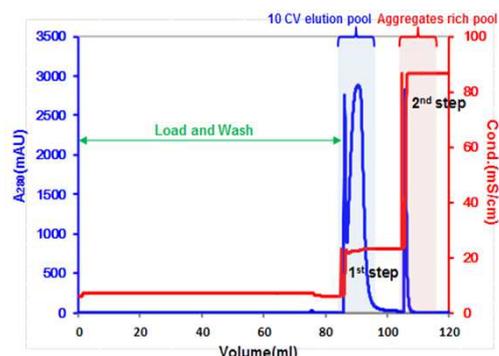


Figure 1. Separation of aggregates by stepwise elution

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		
	Monom er	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)

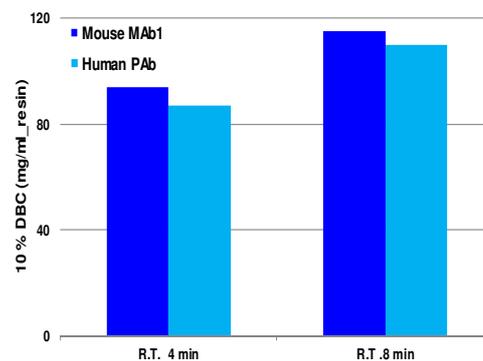


Figure 2. DBC of Cellufine MAX GS for the antibodies

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