Cellufine™ MAX IB

JNC Corporation has developed a new mixed mode resin, Cellufine MAX IB, especially for monoclonal antibody (Mab) polishing after Protein A step. This resin has a salt tolerant polyamine surface modification (see Figure 1) that has been partially modified with butyl groups. This ligand design concept will allow for flexibility in applying, Cellufine MAX IB to a wide range of fields in bio-pharmaceutical purification.

Common Features

- Flow rates up to 500 cm/h at < 0.3 MPa backpressure in a 10-cm diameter column,
- Base CIP with 0.5M NaOH,
- Very stable cross-linked cellulose bead structure.

Cellufine MAX IB Features

- Flow-through polishing format,
- High salt tolerance up to 0.2M NaCl (see Figure 2),
- High clearance of CHO-HCP, leached rProtein A and residual dsDNA (see Figure 3),
- Reduction of Mab aggregates to <1%,
- Rapid two-step capture and polishing workflow format

Figure 1, Ligand Structure of Cellufine MAX IB

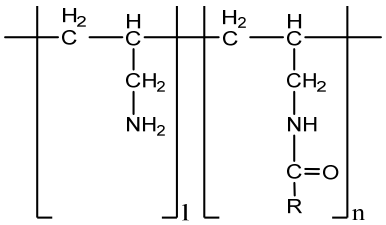
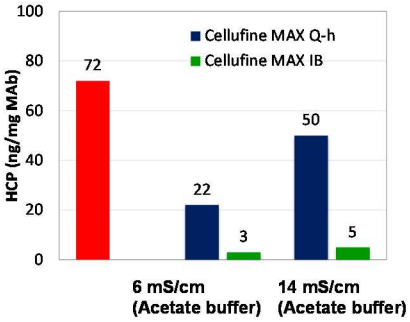


Figure 2, Salt Tolerance of Cellufine MAX IB



CHO-HCP removal by Cellufine MAX IB, MAX Q-h (polymer modified Agarose Q) after rProtein A capture step

Figure 3, Summary of Flow-through polishing of a Mab after rProtein A Capture

- Comparison of Cellufine MAX IB, GS and Polymer Modified Agarose Q

	Elution Buffer from ProA	HCP (ng/mg mAb)	Leak ProA (ng/mg_mAb)	Aggregate (%)	HCD (pg/mg mAb)	Recovery (%)
Loading solution	60 mM Acetate Buffer (pH 3.5)	72	3.0	1.7	10	100
Cellufine MAX Q-h		22	2.1	1.9	＜10	97
Polymer modified Agarose Q		27	2.1	1.8		96
Cellufine MAX IB		3	0.0	1.0		95

This research is partially supported by the developing key technology for discovering and manufacturing pharmaceuticals used for next-generation treatments and diagnoses both from the Ministry of Economy, Trade and Industry, Japan (METI) and from Japan Agency for Medical Research and Development (AMED).