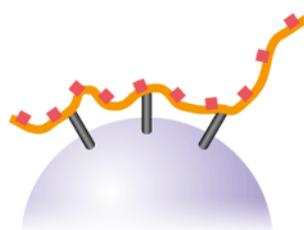


Ion Exchange Chromatography Media

Cellufine MAX S, Q, CM, DEAE

Technical Data Sheet



JNC CORPORATION

Life Chemicals Division

2-1, Otemachi 2-Chome

Chiyoda-ku, Tokyo 100-8105 JAPAN

Phone +81-3-3243-6150 / Fax +81-3-3243-6219

e-mail: cellufine@jnc-corp.co.jp

<https://www.jnc-corp.co.jp/fine/en/cellufine/>

Technical DATA Sheet

Cellufine MAX Ion Exchange Media (S, Q, CM & DEAE)

High Flow Rate, High Binding Capacity

Cellufine MAX is the new, high-flow, Cellufine media. JNC's advanced cross-linking technologies have created more robust base beads operable at high flow and pressure. Further, Cellufine MAX ion exchange (IEX) media are made using surface modification techniques that dramatically increase ligand availability, which translates to higher dynamic binding capacities. Cellufine MAX IEX media are offered in six products, including both anion and cation chemistries

Cellufine MAX base resin

Cellulose, natural polysaccharide, possesses unique crystalline molecular structure differing from non-crystalline polysaccharides such as agarose. Thus Cellufine has unique pore structure as shown in the pictograph (Fig. 1). The new Cellufine MAX series offers the largest pore size of all Cellufine chromatography media. The benefit of such pore size in Cellufine MAX IEX media provides superior strength and excellent mass transfer. This is seen in the break-through curves for huge protein, thyroglobulin, a very large protein (Fig. 2).

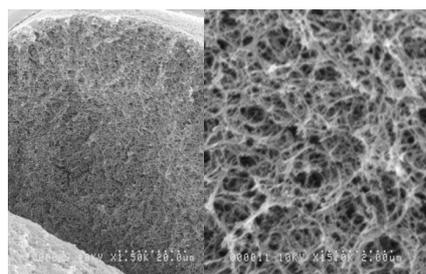


Fig 1. SEM analysis of Cellufine MAX base resin

The differences between X-h and X-r type in Cellufine MAX strong ion exchange media (X) are due to the design of the media. The X-h type is designed for higher binding capacity than the X-r type by optimizing the ligand contents and dextran scaffold.

| | |
|--|--|
| S - strong cation Cellufine MAX S-r Cellufine MAX S-h | |
| CM - weak cation Cellufine MAX CM | |
| Q - strong anion Cellufine MAX Q-r Cellufine MAX Q-h | |
| DEAE - weak anion Cellufine MAX DEAE | |

Fig 3. Ligand structure of Cellufine MAX IEX media

Characteristics of Cellufine MAX IEX Media

The basic characteristics of Cellufine MAX IEX media are shown in Table 1. All Cellufine MAX IEX media are based on 90 μm (average) highly cross-linked cellulose beads, which are surface-modified with dextran. Cellufine MAX IEX media are designed for use of bio-pharmaceuticals manufacturing process.

Pressure-flow Properties of Cellufine MAX IEX Media

Cellufine MAX IEX media enable high-flow operation, which is essential to efficient purification of bio-pharmaceuticals.

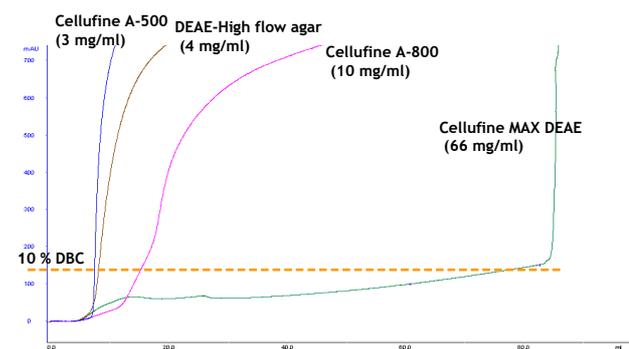


Fig 2. Typical break-through curves for Cellufine DEAE weak anion exchange media with thyroglobulin

Partial Structure of Cellufine MAX IEX Media

Ligand structure for Cellufine MAX IEX media are described in Fig. 3. S, Q, CM and DEAE are correspondingly strong cation, strong anion, weak cation and weak anion exchanger. Two sub-types, h and r are available for Cellufine MAX S and Q.

| | MAX CM | MAX S-r | MAX S-h | MAX DEAE | MAX Q-r | MAX Q-h | |
|--------------------------------------|--|-------------|-------------|-------------|-------------|-------------|-----|
| Matrix | Cross-linked cellulose with dextran scaffold | | | | | | |
| Particle size (µm) | 40 -130 | | | | | | |
| Ligand | CM | S | S | DEAE | Q | Q | |
| Ion exchange capacity (meq / ml-gel) | 0.09 - 0.22 | 0.09 - 0.21 | 0.10 - 0.22 | 0.12 - 0.22 | 0.10 - 0.20 | 0.13 - 0.22 | |
| 10% DBC (mg/ml) | Lysozyme/BSA | 220 | 144 | 191 | 197 | 141 | 225 |
| | human-γ-globulin | 104 | 131 | 216 | 108 | 74 | 135 |
| pH stability | 2 -13 | 2 -13 | 3 -14 | 2 - 12 | 2 - 12 | 2 - 12 | |
| Storage | 20% Ethanol | | | | | | |

Table 1. Characteristics of Cellufine MAX IEX media

The figures below show pressure-flow velocity curves of Cellufine MAX IEX media in a 30 cm column with a 20 cm bed height (Fig. 4). All Cellufine MAX IEX media are operable at practical flow velocities (500 cm/h) and pressures.

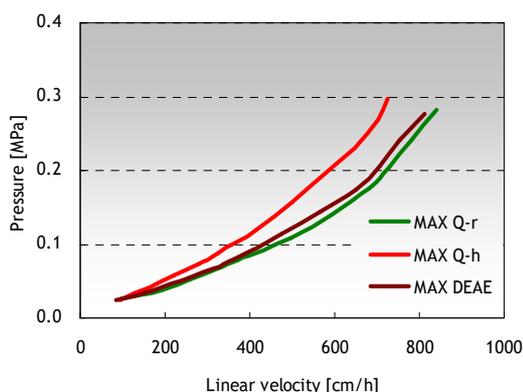
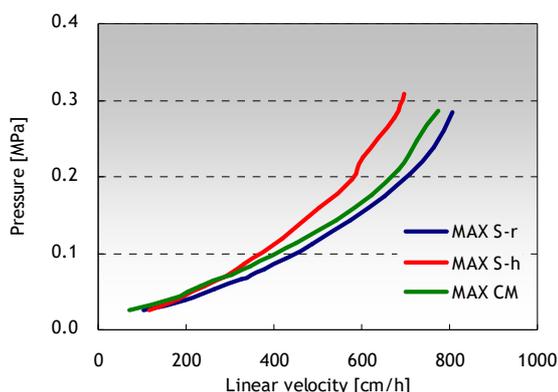


Fig 4. Pressure-flow velocity curves of Cellufine MAX IEX exchange media (30 cm I.D. x 20 cm L), Mobile phase with pure water at 20 °C, Above figure; Cellufine MAX cation exchange media, Below figure; Cellufine MAX anion exchange media

Dynamic Binding Capacities of Cellufine MAX IEX Media

Efficient mass-transfer characteristics of Cellufine MAX IEX media translate to superior dynamic binding capacities (DBC). Figure 5 to 7 show DBC of model proteins at different residence time for Cellufine MAX IEX media. All Cellufine MAX IEX media have a good stability over a range of residence times.

Fig. 8 shows that Cellufine MAX S exhibits superior dynamic binding performance across a range of protein characteristics to competitive media.

These unique characteristics of Cellufine MAX IEX media make it suitable for use in up-stream as well as to down-stream steps in bio-pharmaceuticals purification.

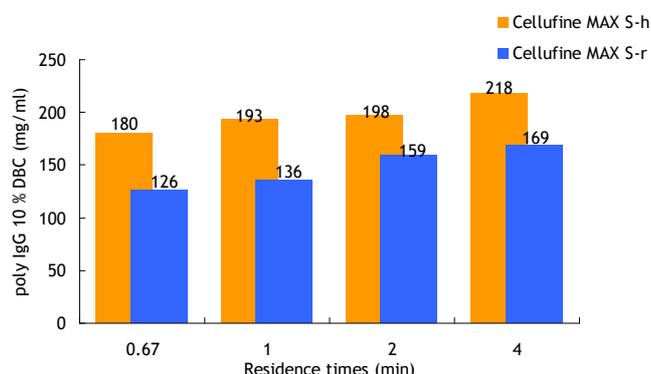


Fig. 5 Residence time vs. IgG-DBC of Cellufine MAX S
 Column: 5 mm ID×100 mm L
 Sample: human polyclonal IgG (1 mg/ml)
 Buffer: 10 mM Acetate-50 mM NaCl (pH 4.3)

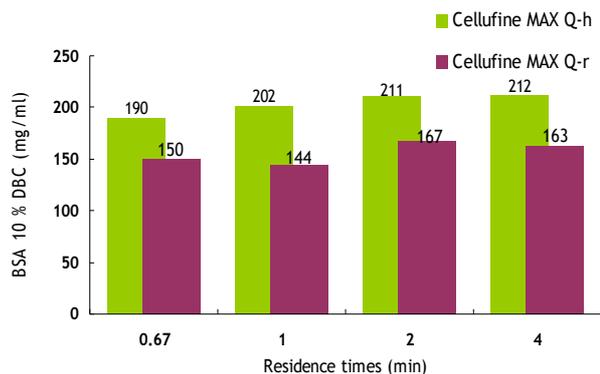


Fig. 6 Residence time vs. BSA-DBC for Cellufine MAX Q
 Column: 5 mm ID × 100 mm L
 Sample: BSA (1 mg/ml)
 Buffer: 50 mM Tris-HCl (pH 8.5)

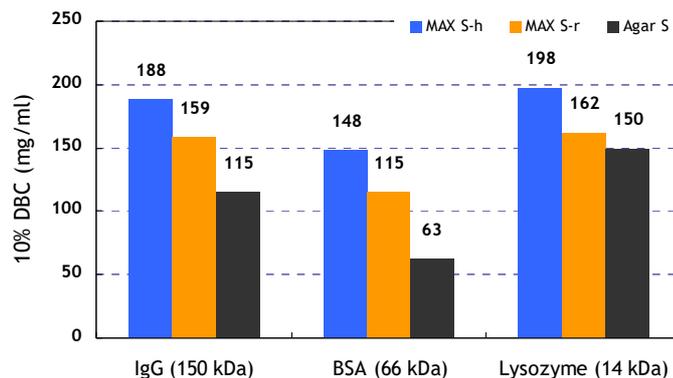


Fig. 8 DBC of Cellufine MAX S and competitive media with various model proteins (R.T.=1 min)
 Polyclonal IgG: 10 mM Acetate (pH 4.3)- 50 mM NaCl
 BSA: 10 mM Acetate (pH 4.3)- 50 mM NaCl
 Lysozyme: Tris-HCl (pH 9.5)

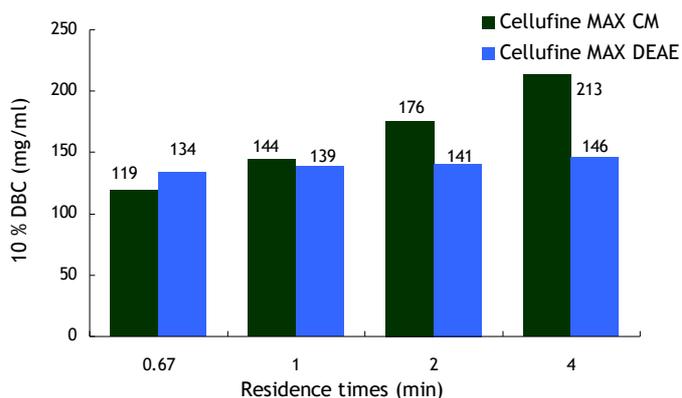


Fig. 7 Residence time vs. DBC for Cellufine MAX CM (polyclonal IgG) and DEAE (BSA)
 Column: 5 mm ID × 50 mm L
 Sample: human polyclonal IgG (1 mg/ml)
 BSA (1 mg/ml)
 Buffer: 10 mM Acetate (pH 5.6) for IgG
 Tris-HCl (pH 8.5) for BSA

Model Proteins Separation Performance for Cellufine MAX IEX Media

Cellufine MAX IEX media are optimized for high adsorption and high resolution. Model protein separation with Cellufine MAX S-h and Cellufine MAX CM (strong cation vs. weak cation) is demonstrated in Fig. 9.

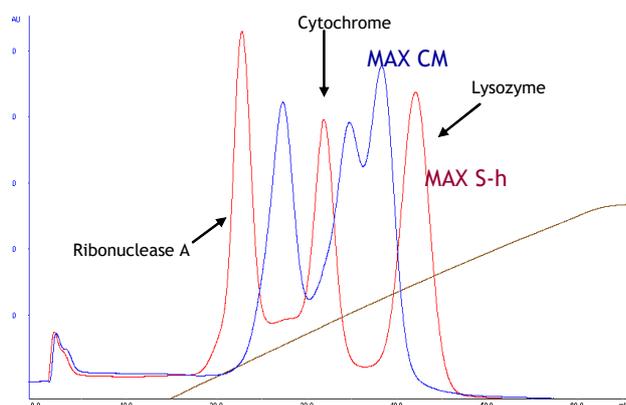


Fig. 9 Model proteins separation for Cellufine MAX S-h and MAX CM

Column: 6.6 mm ID × 50 mm L
 Buffer A: 10 mM phosphate buffer (pH 7)
 Buffer B: 10 mM phosphate (pH 7) + 1 M NaCl
 (0→50 % linear gradient)
 Flow rate: 0.86 ml/min (residence time 2 min)
 Proteins: Ribonuclease A (5 mg/ml),
 Cytochrome C (2.5 mg/ml),
 Lysozyme (1.5 mg/ml)
 Injection volume: 1.5 ml

Chemical Stability and Cleaning-In-Place

Cellulose is well-known as natural products having chemical and physical stability. Thus, since Cellufine is derived from cellulose, it also is stable to chemicals, caustic and acidic solutions. CIP of all Cellufine MAX IEX media can be carried out with 0.5 M NaOH solution. Used media should be stored in 20 % ethanol at 2-25°C after cleaning.

Fig. 10 shows that Model protein separation with Cellufine MAX Q-h and Cellufine MAX DEAE (strong anion vs. weak anion).

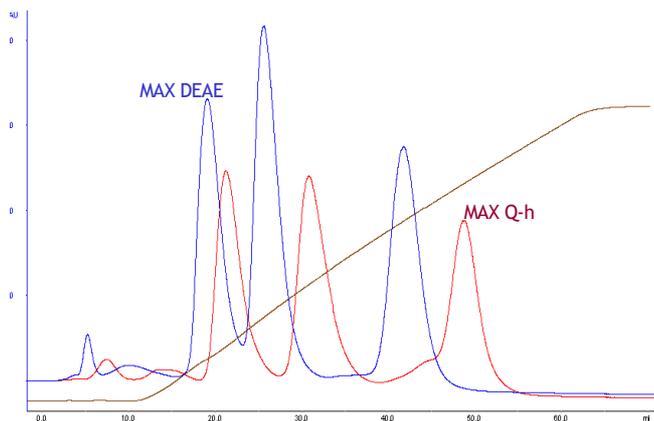


Fig. 10 Model proteins separation for Cellufine MAX Q-h and MAX DEAE

Column: 6.6 mm ID×50 mm L
 Buffer A: 50 mM Tris-HCl (pH 8.5)
 Buffer B: 50 mM Tris-HCl (pH 8.5)- 1 M NaCl
 (0→75 % linear gradient)
 Flow rate: 0.86 ml/min (residence time 2 min)
 Proteins: Transferrin (5 mg/ml),
 BSA (10 mg/ml),
 Pepsin (5 mg/ml)
 Injection volume: 1.5 ml

Ordering Information

| Product Name | Pack Size | Catalogue No. | Product Name | Pack Size | Catalogue No. |
|----------------------|-----------------------|---------------|-----------------------|-----------------------|---------------|
| Cellufine MAX S-r | 1ml x 5 (Mini-Column) | 20300-51 | Cellufine MAX Q-r | 1ml x 5 (Mini-Column) | 20500-51 |
| | 5ml x 5 (Mini-Column) | 20300-55 | | 5ml x 5 (Mini-Column) | 20500-55 |
| | 100 ml | 20300 | | 100 ml | 20500 |
| | 500 ml | 20301 | | 500 ml | 20501 |
| | 5 lt | 20302 | | 5 lt | 20502 |
| | 10 lt | 20303 | 10 lt | 20503 | |
| Cellufine MAX S-h | 1ml x 5 (Mini-Column) | 20400-51 | Cellufine MAX Q-h | 1ml x 5 (Mini-Column) | 20600-51 |
| | 5ml x 5 (Mini-Column) | 20400-55 | | 5ml x 5 (Mini-Column) | 20600-55 |
| | 100 ml | 20400 | | 100 ml | 20600 |
| | 500 ml | 20401 | | 500 ml | 20601 |
| | 5 lt | 20402 | | 5 lt | 20602 |
| | 10 lt | 20403 | 10 lt | 20603 | |
| Cellufine MAX CM | 1ml x 5 (Mini-Column) | 20900-51 | Cellufine MAX DEAE | 1ml x 5 (Mini-Column) | 21000-51 |
| | 5ml x 5 (Mini-Column) | 20900-55 | | 5ml x 5 (Mini-Column) | 21000-55 |
| | 100 ml | 20900 | | 100 ml | 21000 |
| | 500 ml | 20901 | | 500 ml | 21001 |
| | 5 lt | 20902 | | 5 lt | 21002 |
| | 10 lt | 20903 | 10 lt | 21003 | |

Please Send Purchase Orders to:

| | |
|---|--|
| (North America & Europe) JNC America Incorporated 411 Theodore Fremd Avenue, Suite 206 South Rye, NY 10580 USA TEL: 914-921-5400 FAX: 914-921-8822 E-mail: cellufine@jncamericany.com | (Asia & Others) JNC Corporation Life Chemicals Division 2-1, Otemachi 2-Chome, Chiyoda-ku Tokyo 100-8105 Japan Tel: +81-3-3243-6150 Fax: +81-3-3243-6219 E-mail: cellufine@jnc-corp.co.jp |
|---|--|

Please visit our web site for more information
<https://www.jnc-corp.co.jp/fine/en/cellufine/>