

Natrix[®] CH Chromatography Membrane

For single-use flow through aggregate removal

Aggregate removal using cation-exchange (CEX) chromatography can be a significant downstream bottleneck for manufacturers of monoclonal antibodies (mAbs). Natrix® CH chromatography membrane devices address this challenge by removing aggregates via frontal chromatography mode with a loading capacity of up to 1000 g/L and shorter loading times than standard CEX resins. Operating in a frontal chromatography mode also eliminates high salt elution buffers and reduces overall buffer consumption typically associated with a bind and elute CEX chromatography step. If preferred, these single-use chromatography membrane devices can also be used in bind-elute mode for effective aggregate removal. Dependent on your process needs, Natrix® CH chromatography membrane devices deliver improved productivity, flexibility and process robustness.

Key Benefits

Faster Purification
 High binding at high flow rate results in unprecedented productivity compared to standard CFX resin.

• Improved Performance

Unique selectivity provides superior aggregate removal in both frontal or bind and elute modes compared to alternative chromatography membrane devices, across a wide range of operating conditions.

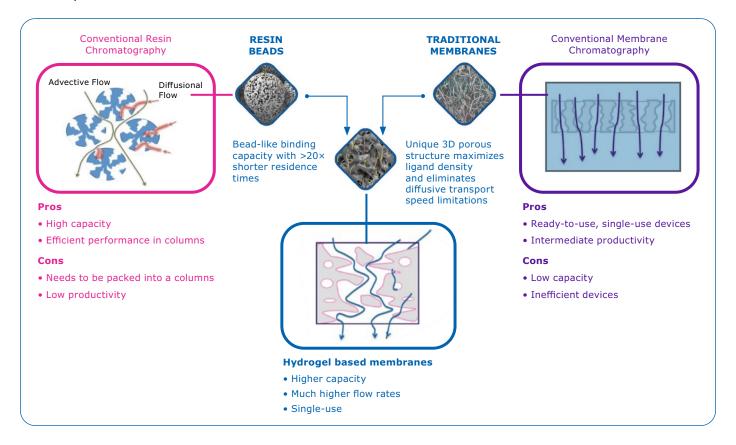
Maximize Efficiency and Flexibility
 Plug-and-play device eliminates column packing and lowers labor costs. The compact size of the devices minimizes facility footprint.





Innovative membrane technology

Natrix® CH chromatography membrane is part of the Natrix® family of single-use chromatography membrane devices. Combining the best of resin beads and traditional membranes, Natrix® chromatography membranes utilize convective mass transfer to achieve high binding at fast flow rates. Compared to resin beads, which rely on slow diffusive mass transfer, Natrix® CH chromatography membrane's mechanism offers faster purification and easy implementation. These characteristics make Natrix® CH chromatography membrane well suited for intensified mAb processes where speed and flexibility are critical. Natrix® CH has a three-dimensional hydrogel membrane structure, which maximizes the surface area and available binding sites, for unprecedented aggregate removal performance.



Technical Information

Definitions

Membrane volume (MV) is the quantity of membrane available for binding within the device. In this document, MV describes both fluid volumes and flow rates (in MV/min). The use of MV is analogous to the use of column volume (CV) in column chromatography.

Natrix® CH membrane primary characteristics

| Membrane material | Polyacrylamide hydrogel (microporous polymer) reinforced with polybutylene terephthalate substrate | |
|-------------------------------------|--|--|
| Ligand/Functional group | 95% Sulfonic acid (strong cation exchanger), 5% t-butyl | |
| Membrane configuration | Flat sheet | |
| Number of layers | 9 | |
| Nominal membrane bed thickness | 1.8 mm | |
| Typical membrane flow pore diameter | 1 μm | |
| Membrane cytotoxicity | ISO 10993-5 | |
| Typical lysozyme binding capacity* | 90 g/L | |
| Typical mAb binding capacity* | 80 g/L | |
| | | |

Natrix® CH membrane primary characteristics

| Typical mAb loading capacity (frontal mode)** | 1000 g/L |
|---|--|
| Chemical compatibility | Compatible w/ most buffers & solvents commonly used in chromatographic biomolecule purification process*** |
| Incompatible chemicals | Hypochlorite (1%), SDS (1%) |
| Shipment conditions | Dry, free of preservatives or wetting agents |
| Storage conditions | Store at room temperature |

Natrix® CH Micro



| Catalogue No. | NXCH002MCR, NXCH010MCR |
|--|--|
| Pack size | 2 devices, 10 devices |
| Nominal unit membrane volume | 1.06 mL |
| Maximum operating pressure & temperature (liquids) | 75 psi/5 bar |
| Nominal unit weight | 10.2 g |
| Height (with Luer caps) | 3.5 cm |
| Height (without Luer caps) | 2.8 cm |
| Diameter | 3.6 cm |
| Connectors | PEEK tubing no less than 0.030 inch internal diameter 2× 10-32 coned adapters 2× 10-32 female to male Luer adapters 2× zero volume Luer connectors |
| Housing material & biological reactivity | Polyethylene/polypropylene copolymer, ISO-10993-5 and USP <87> Cytotoxicity |

Natrix® CH Bench



| Catalogue No. | NXCH001BEN |
|--|---|
| Pack size | 1 device |
| Nominal unit membrane volume | 8.8 mL |
| Maximum operating pressure & temperature (liquids) | 75 psi/5 bar |
| Nominal unit weight | 216 g |
| Length | 11.5 cm |
| Height | 9 cm |
| Depth | 5 cm |
| Connectors | Tubing 1/8 inch O.D. 2× Flangeless male nut 1/8 inch 2× Tubing connectors 1/8 inch 2× PEEK threaded adapters 1/4-28 × 10-32 4× Flangeless Ferrules 1/8 inch |
| Housing material & biological reactivity | Styrene/phenylene ether copolymer, ISO-10993-5 and USP <87> Cytotoxicity |

^{* 10%} breakthrough dynamic binding capacity in 20 mM sodium phosphate buffer, pH 7.0.

** Loading capacity is not limited to 1 kg/L and depends on the feed stream composition and target aggregate removal.

*** Complete & detailed information disclosed in Emprove® dossiers.

Natrix® CH Pilot



| Catalogue No. | NXCH001PLT |
|--|---|
| Pack size | 1 device |
| Nominal unit membrane volume | 124 mL |
| Maximum operating pressure & temperature (liquids) | 75 psi/5 bar |
| Nominal unit weight | 1.3 kg |
| Length | 37.3 cm |
| Height | 22.4 cm |
| Depth | 3.9 cm |
| Connectors | Use Natrix® Process fittings (NXPF001PR0) with Tri-Clamp (TC) connections |
| Housing material & biological reactivity | Styrene/phenylene ether copolymer, ISO-10993-5 and USP <87> Cytotoxicity |

Natrix® CH Process



| Catalogue No. | NXCH001PR0 |
|--|---|
| Pack size | 1 device |
| Nominal unit membrane volume | 372 mL |
| Maximum operating pressure & temperature (liquids) | 75 psi/5 bar |
| Nominal unit weight | 2.6 kg |
| Length | 37.3 cm |
| Height | 22.4 cm |
| Depth | 8 cm |
| Connectors | Use Natrix® Process fittings (NXPF001PR0) with Tri-Clamp (TC) connections |
| Housing material & biological reactivity | Styrene/phenylene ether copolymer, ISO-10993-5 and USP <87> Cytotoxicity |

Natrix® CH device properties

| Device format | Intended use | Flow rate [mL/min] | Typical mAb polishing capacity at 1 kg/L load* [9] | Minimum standardized Lysozyme binding capacity [g] | Nominal membrane volume [mL] |
|------------------------------|---|-----------------------|---|---|---------------------------------|
| Natrix® CH Micro | Screening tool to define optimized OP conditions | ≤10.6 | 1.06 | 0.09 | 1.06 |
| Natrix [®] CH Bench | Medium scale to adjust OP parameters. May be used for small scale clinical runs | ≤88 | 8.8 | 0.79 | 8.8 |
| Natrix® CH Pilot | Clinical & Commercial manufacturing activities | ≤1240 | 124 | 11.2 | 124 |
| Natrix® CH Process | Clinical & Commercial manufacturing activities | ≤3720 | 372 | 33.4 | 372 |

^{*} Based on typical process streams and loading up to 1000 g mAb/L membrane. Loading capacity is not limited to 1000 g/L and depends on the aggregates and impurities content.

Quality Standards and Documentation

Natrix® CH Chromatography membrane devices are part of the Emprove® program that supports product qualification, risk assessment and process optimization. The dossiers consolidate comprehensive product-specific testing data, quality statements, and regulatory information to simplify your compliance needs. Learn more at **SigmaAldrich.com/emprove**.

Ordering information

| Description | Membrane volume [mL] | Quantity/Pack | Catalogue No. |
|----------------------------|----------------------|----------------------|---------------|
| Natrix® CH Micro (2/pack) | 1.06 | 2 | NXCH002MCR |
| Natrix® CH Micro (10/pack) | 1.06 | 10 | NXCH010MCR |
| Natrix® CH Bench | 8.8 | 1 | NXCH001BEN |
| Natrix® Bench holder | - | 1 | NXBH001BEN |
| Natrix® CH Pilot | 124 | 1 | NXCH001PLT |
| Natrix® CH Process | 372 | 1 | NXCH001PR0 |
| Natrix® Process Holder | - | 1 | NXPH001PR0 |
| Natrix® Process Fittings | - | 4 (2 open + 2 blank) | NXPF001PR0 |

For additional information, please visit **SigmaAldrich.com**To place an order or receive technical assistance, please visit **SigmaAldrich.com/offices**

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