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Data Sheet

3M™ Polisher ST

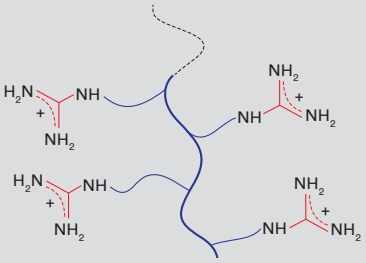
3M™ Polisher ST is a fully encapsulated single-use anion exchange (AEX) product intended to reduce host cell protein (HCP) impurities, viruses, and other negatively charged contaminants in flow-through polishing chromatography of biopharmaceutical process streams. 3M Polisher ST is a synthetic, hybrid purifier containing two complementary AEX-functional media: a quaternary ammonium ("Q") functional nonwoven and a guanidinium (Gu) functional membrane.

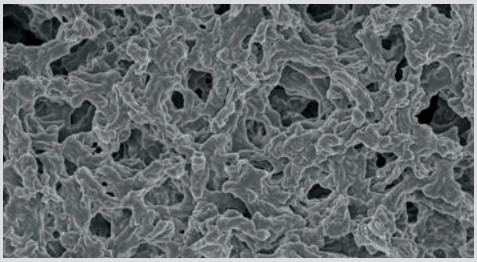
The upstream Q-functional nonwoven provides reduction of turbidity (when present), DNA, and endotoxin, as well as a portion of the product's AEX capacity for HCP and virus reduction. The downstream guanidinium functional membrane layers of 3M Polisher ST are salt tolerant and provide high HCP and virus reduction performance in a wider range of conditions compared to conventional Q-functional AEX resins.

The novel guanidinium functionality of the downstream AEX polishing membrane mimics arginine, one of the three positively charged naturally occurring standard amino acids that make up proteins. The large resonance structure of the guanidium functionality stabilizes the positive charge and is capable of multiple electrostatic-like interactions as well as providing the capability for hydrogen bonding and salt bridging, all of which help with increasing the ligand's salt tolerance. Conventional Q-functional AEX resins and single-use media, which rely solely on electrostatic interactions, can be screened at elevated ionic strength.

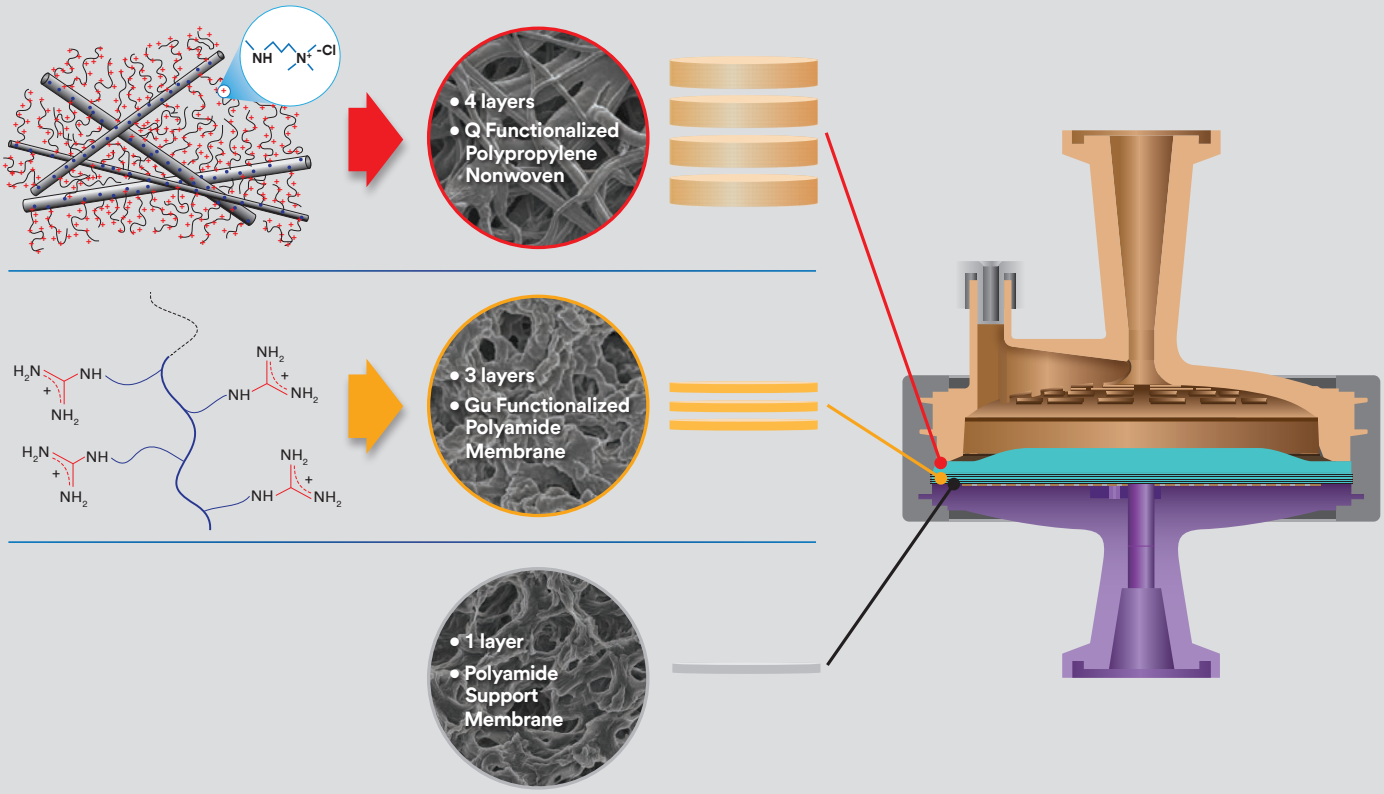
The use of functionalized membranes for high productivity chromatographic purification processes that match upstream efficiency can eliminate the need for oversizing. 3M Polisher ST single use membrane adsorber purification solution is designed for the downstream processing of monoclonal antibodies (mAbs) and other recombinant proteins in flow-through mode. 3M Polisher ST is designed to improve monoclonal antibody (mAb) development and manufacturing processes in traditional polishing process conditions.

3M™ Polisher ST nonwoven and functionalized membrane





The guanidinium functional group ligand is grafted onto a polyamide membrane and follows the classical anion-exchange chromatography mechanism. The downstream polishing process is driven by mAb or therapeutic protein mAb throughput. Membrane chromatography solutions like 3M™ Polisher ST have advantages over columns in flow-through mode for contaminant removal because membranes run at >5 to 10× higher flow rates. Membranes are easy to operate and can be disposed of after one use, just like filters, to save on cleaning and validation cost.

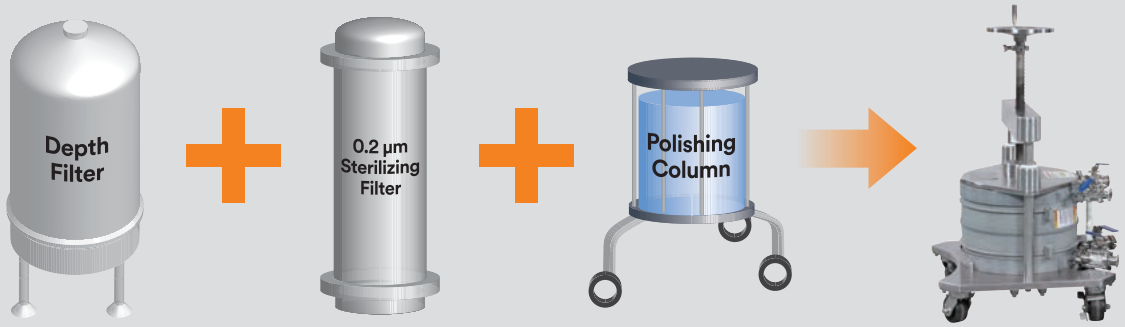


Benefits

3M™ Polisher ST can operate in most process conditions, eliminating the need for depth and membrane filtration post-viral inactivation (VI), allowing process compression. With its combination of high dynamic antibody-loading (10 kg/m²) capacities with low residence time (about 0.2 min compared to 1 minute for chromatography resins), 3M Polisher ST opens the way to an intensified high-productivity, truly single-use purification platform.

3M Polisher ST is a compact, small footprint solution with greater capacity for delivering higher purity and yield in the downstream polishing unit operation, when compared with a traditional chromatographic column, in a connected continuous downstream operation for the flexible facility of the future.

3M Polisher ST allows for a facility strategy that can overcome scale limitations and enable cost-efficient manufacturing to support the growing demand for biologics.



3 process steps into 1: **Depth filter + membrane + AEX column → 3M™ Polisher ST**

*** The smaller footprint of the 3M™ Polisher ST (right) allows for a more streamlined process and efficient use of space.**

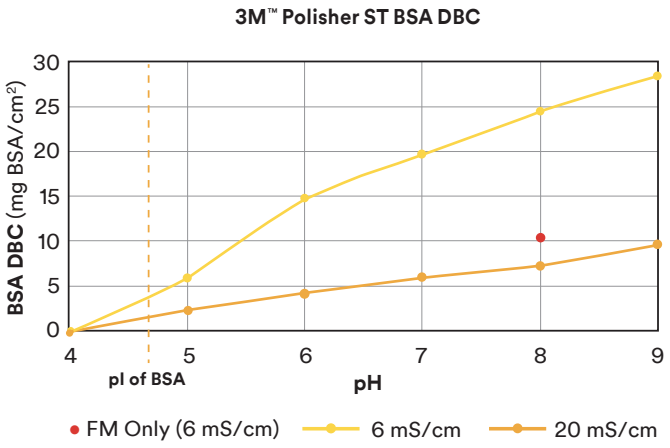
Applications

Ion exchange chromatography is a commonly used downstream polishing purification technique in the production of mAbs and many other therapeutic proteins. The limitation with traditional anion exchange chromatography is that the binding capacity is diffusion-limited and the interaction strength of the ligand depends on operating conditions like pH and conductivity. 3M™ Polisher ST, with its nonwoven and membrane skeletons, provides mechanical strength and durability, while the grafted hydrogel functionality creates a large three-dimensional surface area that contains a high density of functional groups with interconnected pores allowing for convective flow channels which are able to achieve high flow rates.

The high density of binding sites, together with a macroporous structure, enables high binding capacity for not only HCP, but also large molecules, such as viruses and DNA. The high density of binding sites and low residence time results in high mAb recovery (>95%).

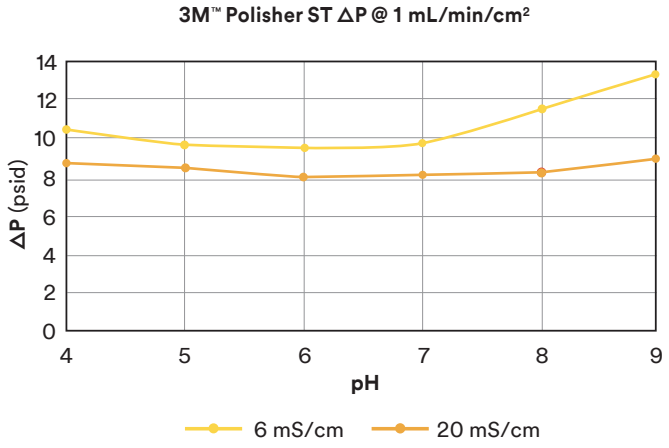
The high ligand density on our advanced anion exchange membrane provides robust impurity removal and viral clearance. It also provides a 50 to 100× higher mAb load capacity than chromatography resin beads, which allows further reduction of the media volume requirement. The impurity clearance performance (HCP ≤1000 ppm, ≤100 ppb DNA, and viral clearance) is independent of the load up to 10 kg/m², enabling downsizing of the unit operation.

BSA Dynamic Binding Capacity – Effects of pH and Conductivity



The BSA Dynamic Binding Capacity (DBC) specification for the functional membrane only is 7.8-12 mg BSA/cm² in 25 mM Tris, pH 8, 50 mM NaCl. High salt (20 mS/cm) reduces the capacity of the membrane by ~ 2-3 mg/cm². Additional capacity provided by the FNW at conductivities < ~10 mS/cm.

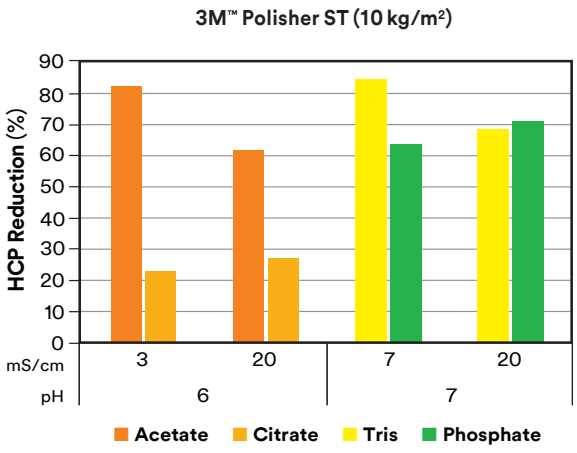
Graph 1: BSA dynamic binding capacity of functional membrane and full construction as a function of pH.



△P specification for the functional membrane only is <10 psid in 25 mM Tris, pH 8, 50 mM NaCl at 1 mL/min/cm². Lower salt (<6 mS/cm) slightly increases pressure due to contribution from functional non-woven. Maximum differential pressure (all capsule sizes) is 35 psid.

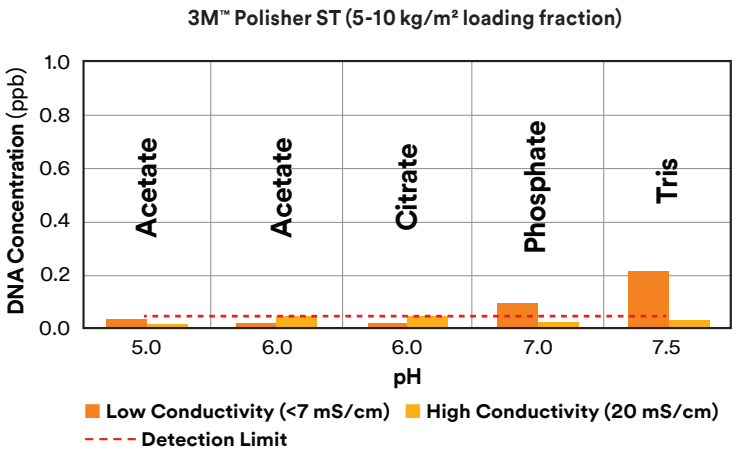
Graph 2: Differential pressure across capsule at 1 mL/min/cm² as a function of pH.

HCP Reduction in Monovalent and Polyvalent mAb Solutions



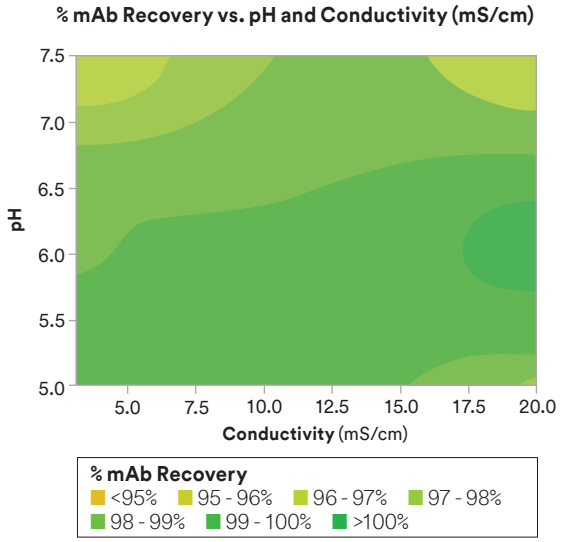
Graph 3: HCP reduction in mAb solution by 3M™ Polisher ST as a function of conductivity, pH and buffer.

DNA Reduction in mAb Solutions

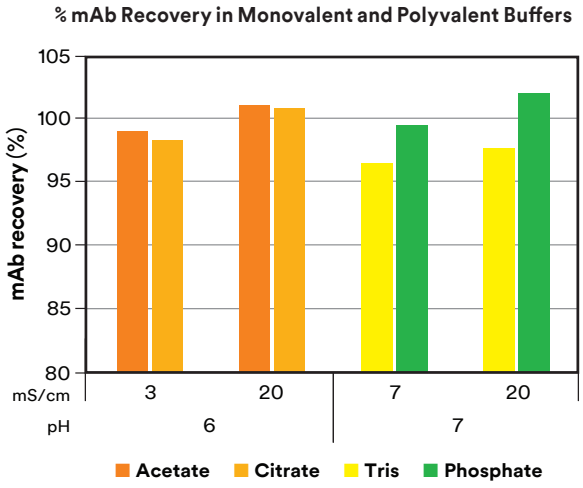


Graph 4: Residual DNA concentrations post 3M™ Polisher ST for different test conditions.

mAb Recovery in Monovalent and Polyvalent Buffers



Graph 5: mAb recovery as a function of pH and conductivity, Acetate/Tris buffer.



Graph 6: mAb recovery as a function of pH and conductivity, Acetate/Tris buffer.

Viral Clearance in 6 Model mAb Feed Streams

Viral Clearance studies were performed with MVM and XMuLV using mAb solutions representing model feed streams. The Tris pH 7.5, 5 mS/cm MVM study was performed at Charles River. All other studies were performed at Texcell.

Buffer	pH	Conductivity	Turbidity	Target HCP ppm	Target DNA ppb	Average Viral Clearance (LRV)			
						MVM		XMuLV	
						0-5 kg/m²	5-10 kg/m²	0-5 kg/m²	5-10 kg/m²
Tris	7.5	5	No	200	20	6.16	6.53	>6.26	>6.26
Phosphate	7.5	20	No	200	20	>4.69	>7.45	>6.61	>6.89
Acetate	5.5	5	Yes	500	1000	5.34	5.86	>6.53	>7.54
Citrate	5.5	5	No	500	50	5.33	6.14	6.16	4.74
Tris	7.0	7	No	500	50	5.60	6.05	>6.88	6.41
Acetate	6.0	7	No	500	50	>5.43	5.92	>6.72	>7.72

>4 LRV viral clearance was shown for all mAb feed streams.

Table 1: Viral clearance of MVM and XMuLV by 3M™ Polisher ST in different model mAb solutions.

Benefits:

- Operates in robust process conditions (pH 5.0 to 9.0 and conductivity 3 to 20 mS/cm)
- HCP reduction >60% reduction in Phosphate buffer, >22% reduction in Citrate buffer
- Viruses reduction >4 log
- DNA clearance down to LOD levels (~0.05ppb DNA)
- Easy to use: elimination of column packing, unpacking, cleaning and storage
- Enables downstream process intensification through combination of high flow rates with high binding

Product Specifications

Product Selection/ Specification

Product Name	BC1	BC4	BC25		BC170	BC340	BC1020	BC2300	BC16000
Model Name	EMP101STX080R	EMP201STX080R	EMP301STX080R	EMP303STX080R	EMP503STX080R	EMP513STX080R	EMP533STX080R	EMP710STX080R	EMP770STX080R
Part Number	70-0203- 4696-4	70-0203-4697-2	70-0203-4698-0	70-0203-4700-4	70-0203-4701-2	70-0203-4702-0	70-0203-4703-8	70-0203-4704-6	70-0203-4913-3
Global Part Number	7100228760	7100228761	7100179207	7100179209	7100179230	7100179229	7100179560	7100179570	7100182144
Height × Diameter	4.8 cm × 4.3 cm (1 7/8 × 1 11/16 in.)	5.9 × 4.3 cm (2.3 × 1.7 in.)	4.5 × 7.7 cm (1.7 × 3.0 in.)	8.8 × 7.7 cm (3.5 × 3.0 in.)	10.1 × 24.1 cm (4.1 × 9.5 in)		15.2 × 24.1 cm (6.0 × 9.5 in.)	7.6 cm x 45 cm (3 × 17 ¾ in.)	22.2 cm x 45 cm (8 ¾ x 17 ¾ in.)
Dry Weight	10 g	15.5 g	72 g	78 g	1.1 kg	1.2 kg	1.8 kg	3.8 kg	12.7 kg
Weight Wet Post Blow Down	10.5 g	17.5 g	88 g	94 g	1.2 kg	1.3 kg	2.3 kg	4.6 kg	18.5 kg
Fill Volume[1]	1.8 mL	5.6 mL	40 mL	45 mL	730 mL	730 mL	1.7 L	4.4 L	19.8 L
Hold up Volume Post Blow Down[2]	0.7 mL	1.8 mL	16 mL	16 mL	70 mL	110 mL	460 mL	0.8 L	5.8 L
Capsule Material	Polypropylene				Polysulfone			Glass-Filled Polyphenylene Ether/ Polystyrene	
Sterilization Pre Use	121°C for 30 minutes using Pre-vac cycle						121°C for 40 minutes using Pre-vac cycle	121°C for 30 minutes using Pre-vac cycle	121°C for 40 minutes using Pre-vac cycle
Sterilization Post Use	Post use 1 autoclave cycle at 126°C for 30 minutes								
Alkaline Resistance Pre Use	1M Sodium Hydroxide (NaOH) for 60 minutes								
Alkaline Resistance Post Use	1M Sodium Hydroxide (NaOH) or 5% Bleach (NaClO)								
Inlet/Outlet Connections	Luer	Luer	Luer	¾ in. Sanitary				1 ½ in. Sanitary	
Maximum Inlet Pressure[3]	3.4 bar (50 psig)		2.8 bar (40 psig)		3.1 bar (45 psig)			3.4 bar (50 psig)	
Maximum Differential Pressure	2.4 bar (35 psig)								
Maximum Temperature	40°C (104°F)								
Required Preconditioning Flush Volume[4]	5 mL	20 mL	125 mL		0.9 L	1.8 L	5.5 L	12 L	85 L
Recommended Use Flow Rate	1 mL/min	4 mL/min	25 mL/min		170 mL/min	340 mL/min	1020 mL/min	2.3 L/min	16 L/min
Storage Conditions	Controlled indoor temperature: 0 - 30°C (32 - 86°F) in original packaging								
Shelf Life[5]	2 years from date of manufacture @ 30°C maximum storage temperature								

For more information about the 3M™ Polisher ST, contact your local sales rep by calling 1800-425-3030 , or visiting us at https://www.3mindia.in/3M/en_IN/bioprocessing-in/products-solutions/polisher-st/

1. Fill Volume is defined as the volume of liquid that is required to fill the capsule.
2. Post Blow-Down Hold-Up Volume is defined as the volume of the residual liquid after air/gas blow down.
3. Do not use this product for continuous service with compressed gasses. The use of compressed gas is permissible for post-use integrity testing and blow down purposes.
4. A Preconditioning Flush is required for the product to be compliant with USP Biological Reactivity Tests, including USP <87> and <88> Class VI. The Required Preconditioning Flush is an aqueous solution, having a minimum conductivity of 3 mS/cm. DO NOT use water to flush the capsule. Refer to Installation and Operation Instructions for complete instructions on how to perform the preconditioning flush.

Intended Use: 3M™ Polisher ST single-use filter products are intended for use in biopharmaceutical processing applications of aqueous based pharmaceuticals (drugs) and vaccines in accordance with the product instructions and specifications, and cGMP requirements, where applicable. Since there are many factors that can affect a product's use, the customer and user remain responsible for determining whether the 3M product is suitable and appropriate for the user's specific application, including user conducting an appropriate risk assessment and evaluating the 3M product in user's application.

Prohibited Use: 3M advises against the use of these 3M products in any application other than the stated intended use(s), since other applications have not been evaluated by 3M and may result in an unsafe or unintended condition. Do not use in any manner whereby the 3M product, or any leachable from the 3M product, may become part of or remains in a medical device that is regulated by any agency, and/or globally exemplary agencies, including but not limited to: a) FDA, b) European Medical Device Directive (MDD), c) Japan Pharmaceuticals and Medical Devices Agency (PMDA) or in applications involving permanent implantation into the body; Life-sustaining medical applications; Applications requiring food contact compliance.

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