Science.
Applied to Life.™

Data Sheet

3M™ Emphaze™ AEX Hybrid Purifier

The 3M™ Emphaze™ AEX Hybrid Purifier is improving biopharmaceutical manufacturing processes, including recombinant protein and especially monoclonal antibody (mAB).

The 3M Emphaze AEX Hybrid Purifier is a synthetic, multi-mechanism single-use purifier used for biopharmaceutical clarification. It delivers consistent, high-purity clarified process fluid by reducing negatively charged DNA, HCP, endotoxin, and cell debris through a combination of chromatographic and size exclusion mechanisms.

Performance

In a representative monoclonal antibody (mAb) manufacturing process, when used in combination at the clarification stage with Zeta Plus™ depth filters and LifeASSURE™ membrane filters, the Emphaze AEX Hybrid Purifier increases process efficiency and protein purity post Protein A.

Customers experience benefits in typical monoclonal antibody purification processes using the Emphaze AEX Hybrid Purifier.

- Nominal 20-40% HCP and greater than 4 log DNA reduction
- Consistent output turbidity (<5 NTU)
- Increase product purity post-protein A
- Downsizing of the sterilizing grade membrane
- Reduce turbidity post viral inactivation/ neutralization step
- Reduce impurities load on downstream AEX column

Sterilization/Sanitization

Emphaze AEX Hybrid Purifier products, listed in Table 1, can be sterilized or sanitized. Refer to Table 1 on page 3 for more information.

As we worked with customers to qualify the Emphaze AEX Hybrid Purifier, we heard that sterilization/ sanitization compatibility is an important feature. We announced that 3M Emphaze AEX Hybrid Purifier, with part and model numbers that end in an R, can be sterilized/sanitized across various aqueous-based biopharmaceutical processes, including vaccine purification. See Table 1 for the product names and numbers.

Note: Only these products can be sterilized and sanitized.

Figure 1
Four layers of Q-functional nonwoven media

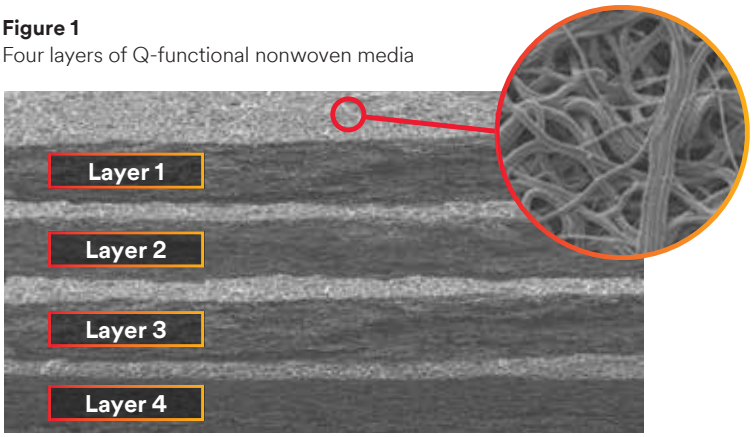
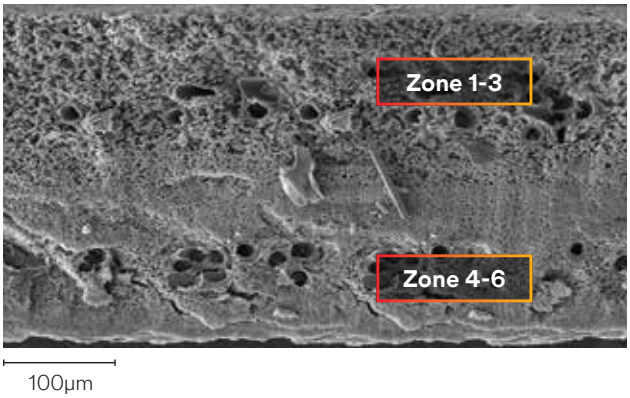


Figure 2
Highly asymmetric 0.2µ membrane



Benefits

High-performance clarification

- >4 log DNA reduction
- Consistent output turbidity (<5 NTU)
- Nominal 20-40% HCP

Enables higher Protein A column performance over 3M depth filtration

- >10x less HCP post-Protein A
- >1,000x DNA reduction post-Protein A
- >10x less residual contaminants on Protein A column

Enables

- Significant reduction in filter surface area for sterilizing filters

Provides

- >10x less HCP and DNA entering downstream AEX column

Increased process efficiency

- Simplify the process by removing multiple types of impurities in a single process step, leading to better process economics.
- The combination of 3M's Zeta Plus™ Series Depth Filter, Emphaze™ AEX Hybrid Purifier and LifeASSURE™ Membrane filters may be a compelling alternative to a centrifuge-based harvest-clarification process.

Increase product purity over harvest-clarification unit operations (centrifuge + 3M depth filter or 2 stage 3M depth filters)

- Removing more impurities early in the process, the Emphaze AEX Hybrid Purifier delivers reduced DNA, HCP and cell debris load to chromatography columns.

Introducing two laboratory capsules (BV0.3 and BV1)

Small laboratory capsules (Figure 3) designed for early stage discovery and low volume clarification (~20–80mL).

Figure 3

3M™ Emphaze™ AEX Hybrid Purifier BV0.3

3M™ Emphaze™ AEX Hybrid Purifier BV1

Re-introduced in September 2018, BV60 scale-up capsule

We also heard that the scale-up capsule BV60 size is needed for process scale-up.

Introduced in September 2018, sterilization and sanitizing compatibility, including 16" production capsules and manifolds

3M™ Emphaze™ AEX Hybrid Purifier can be sanitized* for deployment across various aqueous-based biopharmaceutical processes, including vaccine purification. The suggested protocol for caustic sanitization is 1.0M NaOH for 60 minutes (follow operating instructions).

Emphaze AEX Hybrid Purifer can be sterilized. The suggested protocol for autoclaving is at 121°C. Follow operating instructions for suggested protocol.

*Only these products can be sanitized and sterilized. See Table 1 on the next page.

More efficient process with less turbid post Protein A elute.

Product Selection/Specification

(NOTE: R after product and model name indicates the sterilization/sanitization compatible products)

Product Name		BV0.3R	BV1R	BV8R		BV60R	BV120R	BV360R	BV800R	BV5600R
Model Name		EMP101AEX020R	EMP201AEX020R	EMP301AEX020R	EMP303AEX020R	EMP503AEX020R	EMP513AEX020R	EMP533AEX020R	EMP710AEX020R	EMP770AEX020R
Part Number		70020346857	70020346865	70020346873	70020346881	70020346899	70020346907	70020346915	70020346923	70020346931
Global Part Number		7100179206	7100174193	7100158433	7100158434	7100158416	7100166976	7100158435	7100158436	7100158437
Height x Diameter		4.8 × 4.3 cm (1.9 × 1.7 in.)	5.9 × 4.3 cm (2.3 × 1.7 in.)	4.5 × 7.7cm (1.7 × 3.0 in.)	8.8 × 7.7cm (3.5 × 3.0 in.)	10.3 × 21.6cm (4.1 × 6.5 in.)		15.2 × 21.6cm (6.0 × 6.5 in.)	5.7 × 45.2cm (2.2 × 17.8 in.)	20.3 × 45.2cm (8.0 × 17.8 in.)
Dry Weight		9.0 g	14.5 g	71g	77g	1.0kg	1.1kg	1.6kg	3.4kg	9.5kg
Weight Wet Post Blow Down		9.5 g	16.0 g	80g	85g	1.1kg	1.2kg	2.1kg	4.1kg	14.2kg
Fill Volume[1]		2.0 mL	5.5 mL	13mL	16mL	0.55L	0.55L	1.4L	3.4L	10.6L
Hold up Volume Post Blow Down[2]		0.5 mL	1.5 mL	9mL	9mL	0.10L	0.15L	0.46L	0.70L	4.7L
Capsule Material		Polypropylene		Polypropylene, Glass Filled Polypropylene		Polysulfone, Polypropylene, Thermoplastic Elastomer, Fluorocarbon			Thermoplastic Elastomer, Glass Filled Polypropylene Oxide, Polystyrene, Silicone	
Autoclave Cycle	Sterilization Pre-Use	121°C, 30 min	121°C, 30 min	121°C, 30 min		121°C, 30 min	121°C, 30 min	121°C, 40 min	121°C, 40 min	121°C, 40 min
Autoclave Cycle	Sterilization Post Use	121°C, 40 min	121°C, 40 min	121°C, 40 min		121°C, 40 min	121°C, 40 min	121°C, 40 min	121°C, 40 min	121°C, 40 min
Alkaline Resistance	Pre-Use	1M NaOH soak for 1 hour at ambient temperatures followed by gravity drain to remove excess base; **DO NOT BLOW DOWN**								
Alkaline Resistance	Post Use	Capsule soak for 1 hour with 1M NaOH or 5% NaClO (bleach)								
Inlet/Outlet Connections		Luer-Lok			3/4 in. Sanitary Connectors				1-1/2 in. Sanitary Connectors	
Maximum Inlet Pressure[3]		3.4 bar		2.8 bar		3.1 bar			3.4 bar	
Maximum Differential Pressure		2.4 bar		2.4 bar		2.4 bar	2.4 bar	2.4 bar	2.4 bar	2.4 bar
Maximum Temperature		40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)	40°C (104°F)
Required Preconditioning Flush Volume[4]		6.5 mL	22 mL	130mL		0.9L	1.8L	5.5L	12L	85L
Recommended Use Flow Rate		0.4 mL/min	1.4 mL/min	8mL/min		50mL/min	100mL/min	300mL/min	680mL/min	4700mL/min
Storage Conditions		Controlled indoor temperatures: 0–30°C (32–86°F) in original sealed packaging								
Shelf Life		Up to 2 years from date of manufacture @ 30°C maximum storage								

A full support package is available for the 3M™ Emphaze™ AEX Hybrid Purifier. This package includes Installation and Operation Instructions, Certificate of Quality or Certificate of Lot Conformance, and a Regulatory Support File.

1. Capsule 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 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 flush solution can be a buffer or 25–150mM sodium chloride solution. Refer to Installation and Operation Instructions for complete instructions on how to perform the preconditioning flush.

Compliance

- USP <87> Biological Reactivity Tests, In Vitro: All wetted component materials of the 3M™ Emphaze™ AEX Hybrid Purifier products were tested and met the requirements of USP <87> Biological Reactivity Tests, In Vitro. The media was subjected to the required preconditioning flush prior to testing.
- USP <88> VI Biological Reactivity Tests, In Vivo: All wetted component materials of the 3M™ Emphaze™ AEX Hybrid Purifier products were tested and met the requirements of USP <88> Biological Reactivity Tests, In Vivo. The media was subjected to the required preconditioning flush prior to testing.

Animal-Derived Material Statement: In order to assess the BSE/TSE risk associated with the 3M Emphaze AEX Hybrid Purifier products, we have contacted our suppliers of raw materials and performed an evaluation of our production processes to determine if any of the materials used are of animal origin. The result of our survey and inquiries of our raw material suppliers has revealed that the polypropylene resins used in the nonwovens and the glass-filled polyphenylene oxide/polystyrene resin used in molded parts may contain tallow. Our suppliers have indicated that these parts that use tallow derivatives are processed at conditions conforming to the requirements of the European Medicines Agency note for guidance EMEA/410/01 rev.3.

Intended Use: Single-use processing of aqueous based biological pharmaceuticals (drugs) and vaccines to remove biological contamination strictly following the product operation instructions and cGMP requirements, where applicable.

Prohibited Use: As a component 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 Regulation (MDR), c) Japan Pharmaceuticals and Medical Devices Agency (PMDA); Applications involving permanent implantation into the body; Life-sustaining medical applications; Applications requiring FDA Food Contact or comparable compliance.

Product Selection and Use: Many factors beyond 3M's control and uniquely within user's knowledge and control can affect the use and performance of a 3M product in a particular application. As a result, end-user is solely responsible for evaluating the product and determining whether it is appropriate and suitable for end-user's application, including completing a risk assessment that considers the product leachable characteristics and its impact on drug and other safety conducting a workplace hazard assessment and reviewing all applicable regulations and standards (e.g., OSHA, ANSI, etc.). Failure to properly evaluate, select, and use a 3M product and appropriate safety products, or to meet all applicable safety regulations, may result in injury, sickness, death, and/or harm to property.

Warranty, Limited Remedy, and Disclaimer: 3M warrants that each 3M product meets the applicable 3M product specification at the time 3M ships the product. 3M MAKES NO OTHER WARRANTIES OR CONDITIONS, EXPRESS OR IMPLIED,INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, FITNESS FOR APARTICULAR PURPOSE, OR ARISING OUT OF A COURSE OF DEALING, CUSTOM, OR USAGE OF TRADE WITH RESPECT TO THE INFORMATION PROVIDED AND THE PRODUCT THE INFORMATION REFERS TO. If a 3M product does not conform to this warranty, then the sole and exclusive remedy is, at 3M's option, replacement of the 3M product or refund of the purchase price.

Limitation of Liability: Except for the limited remedy stated above, and except to the extent prohibited by law, 3M will not be liable for any loss or damage arising from or related to the 3M product, whether direct, indirect, special, incidental, or consequential (including, but not limited to, lost profits or business opportunity), regardless of the legal or equitable theory asserted, including, but not limited to, warranty, contract, negligence, or strict liability.

3M Separation and Purification Sciences Division

3M Nederland BV
Molengraaffsingel 29
2629 JD, Delft
Tel. (+31) 015 78 22 333
Email: 3MPurification.bnl@mmm.com
http://go.3M.com/biopharma_NL

3M Belgium bvba/sprl
Hermeslaan 7
1831, Diegem
Tel. (+32) 02 722 51 11
Email: 3MPurification.bnl@mmm.com
http://go.3M.com/biopharma_frBE
http://go.3M.com/biopharma_nlBE

3M Österreich GmbH
Kranichberggasse 4
1120, Wien
Tel. (+49) 02 13 11 40
Email: filter.de@mmm.com
http://go.3M.com/biopharma_DE

3M Deutschland GmbH
Carl-Schurz-Straße 1
41460, Neuss
Tel. (+49) 02 13 11 40
Email: filter.de@mmm.com
http://go.3M.com/biopharma_DE

3M Schweiz GmbH
Eggstrasse 93
8803, Rüschlikon
Tel. (+49) 02 13 11 40
Email: filter.de@mmm.com
http://go.3M.com/biopharma_DE