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3M Separation and Purification Sciences Division
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 removing soluble and insoluble impurities, such as DNA, HCP, and cell debris, through a combination of chromatographic and size exclusion mechanisms.

As we worked with customers to qualify the Emphaze AEX Hybrid Purifier, we heard that sterilization/sanitization compatibility is an important feature. We are announcing 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.

Sterilization/Sanitization

Emphaze AEX Hybrid Purifier products, listed in Table 1, can be sterilized or sanitized by the following methods.

- Autoclave @ 121°C, 30-minute cycle, pre-use
- 1.0M NaOH Sanitization, 60 minutes

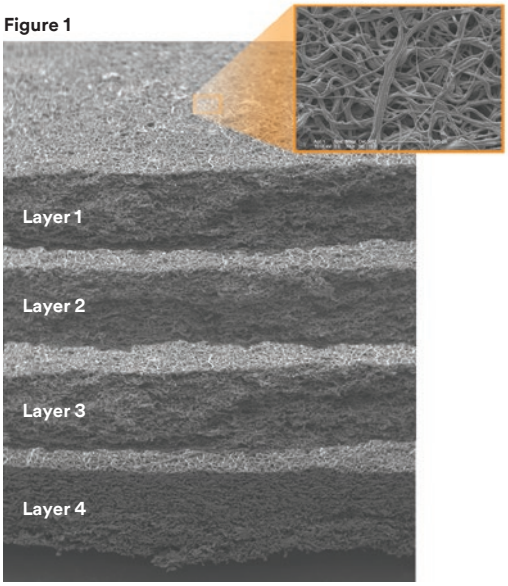
Performance

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.

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

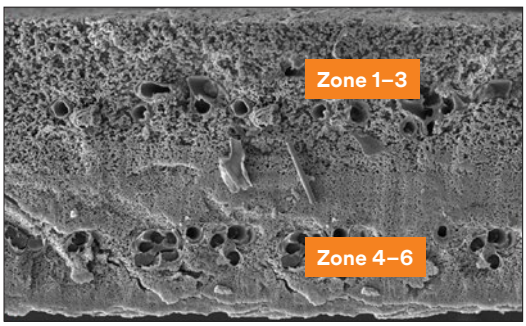
- Nominal 30% HCP and greater than 4 log DNA reduction
- Consistent output turbidity (<5 NTU)
- Increase product purity post-protein A
- Downsizing of the sterilizing grade membrane
- Reduce turbidity post viral inactivation/neutralization step
- Reduce impurities load on downstream AEX column

Figure 1



Four layers of Q-functional nonwoven media

Figure 2



Highly asymmetric 0.2m membrane

Benefits

(Experienced in a typical mAb harvest-clarification unit operation)

High performance clarification

- >4 log DNA reduction
- Consistent output turbidity (<5 NTU)
- Nominal 30% HCP

Enables higher Protein A column performance over traditional 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 contaminants 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 traditional harvest-clarification unit operations (centrifuge + depth filter or 2 stage depth filters)

Removing more impurities early in the process, the Emphaze AEX Hybrid Purifier provides protection to chromatography columns increasing their purification performance.

Introducing two laboratory capsules (BV0.3 and BV1)

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

Re-introducing the BV60 scale-up capsule

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

Introducing 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.

In addition to sanitizing compatibility, Emphaze AEX Hybrid Purifier products can be sterilized.* The suggested protocol for autoclaving is @ 121°C, 30-minute cycle, pre-use.

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

Figure 3

3M™ Emphaze™ AEX Hybrid Purifier BV0.3

3M™ Emphaze™ AEX Hybrid Purifier BV1

Compliance

- USP <87> Biological Reactivity Tests, *In Vitro*: All wetted components of the 3M Emphaze AEX Hybrid Purifier products are in compliance with the USP <87> requirements.
- USP <88> VI Biological Reactivity Tests, *In Vivo*: All wetted components of the 3M Emphaze AEX Hybrid Purifier products are in compliance with the USP <88> Class VI-70°C Requirements.

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 which use tallow derivatives and stearic acid are processed at conditions conforming to the requirements of the European Medicines Agency note for guidance EMEA/410/01 rev.3.

Table 1

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		TBD	TBD	7100158433	7100158434	7100158416	7100166976	7100158435	7100158436	7100158437
Height x Diameter		3.0 × 2.2cm (1.2 × 0.9 in.)	4.8 × 3.7cm (1.9 × 1.5 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		4.1g	10.3g	71g	77g	1.0kg	1.1kg	1.6kg	3.4kg	9.5kg
Weight Wet Post Blow Down		4.5g	12.1g	80g	85g	1.1kg	1.2kg	2.1kg	4.1kg	14.2kg
Fill Volume[1]		0.7mL	4.1mL	13mL	16mL	0.55L	0.55L	1.4L	3.4L	10.6L
Hold up Volume Post Blow Down[2]		0.4mL	1.8mL	9mL	9mL	0.10L	0.15L	0.46L	0.70L	4.7L
Capsule Material		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, 30 min	121°C, 30 min	121°C, 30 min
	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**								
	Post Use	Capsule soak for 1 hour with 1M NaOH or 5% NaClO (bleach)								
Inlet/Outlet Connections		Luer-Lok	Luer-Lok	Luer-Lok	3/4 in. Sanitary Connectors				1-1/2 in. Sanitary Connectors	
Maximum Inlet Pressure[3]		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	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]		5mL	16mL	130mL		0.9L	1.8L	5.5L	12L	85L
Recommended Use Flow Rate		0.3mL/min	1mL/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[5]		Up to 2 years from date of manufacture @ 30°C maximum storage								

A full support package is available for the Emphaze™ AEX Hybrid Purifier. This package includes Installation and Operation Guides, Certificates of Quality or Certificates 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 USP36 <87> and <88> Class VI. The flush solution can be a buffer or 25–150mm sodium chloride solution. Refer to User Manual for complete instructions on how to perform the preconditioning flush.
5. Emphaze AEX Hybrid Purifiers are designed to maintain USP36 <88> Class VI compliance and high adsorption capacity for up to 2 years from date of manufacture. Product labeling includes the expiration date.

Product Use

Intended uses

Single use processing of aqueous based biological pharmaceuticals (drugs) and vaccines strictly following the product operating instructions and cGMP requirements, where applicable. Customers must determine whether the 3M product is suitable for a specific application based on a risk assessment that considers the product leachable characteristics and its impact on drug safety.

Prohibited uses

Prohibited for 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) US Food and Drug Agency (FDA), b) European Medical Device Regulation (MDD), c) Japan PMDA; in applications involving permanent implantation into the body; in life-sustaining medical applications; in applications requiring FDA Food Contact compliance.

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