Science.
Applied to Life.™

Product Information Sheet

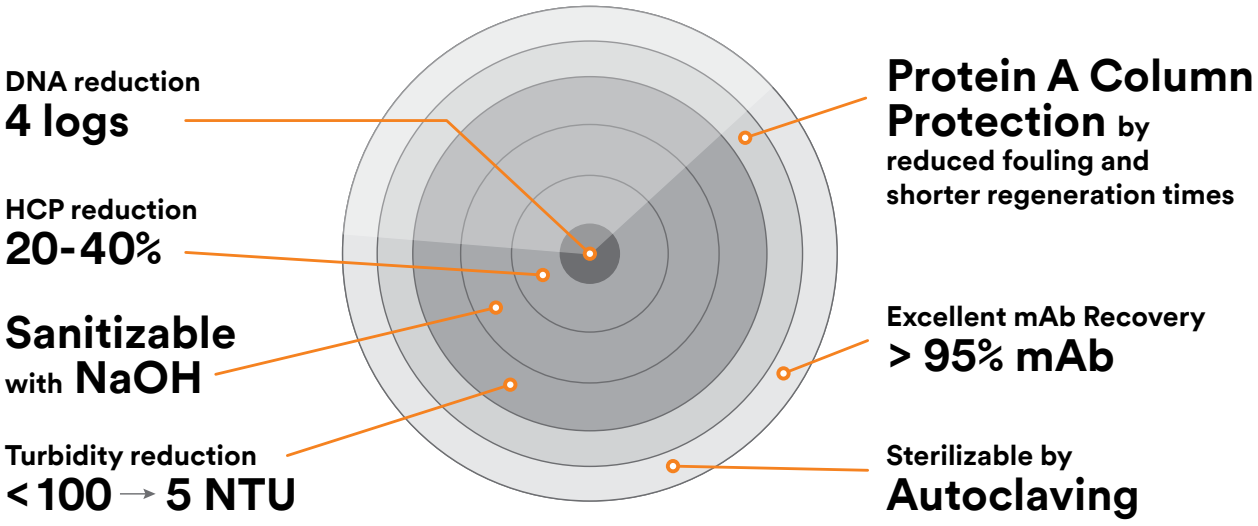
3M™ Emphaze™ AEX Hybrid Purifier

One step to increase efficiency

The 3M™ Emphaze™ AEX Hybrid Purifier is a synthetic, single-use chromatographic 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 chromatographic mechanism.

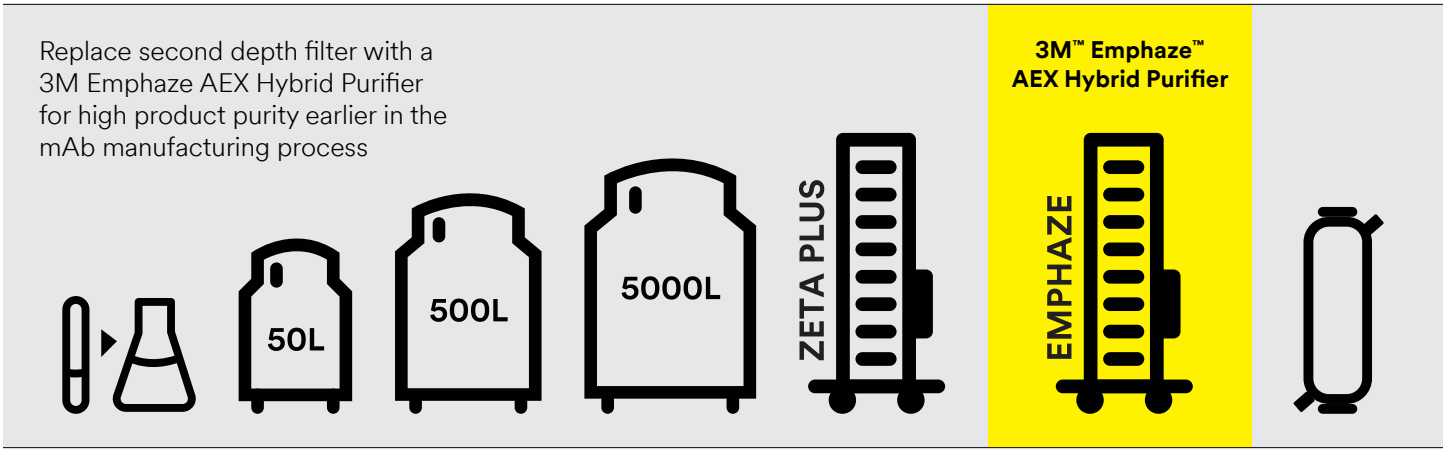
Integrating 3M Emphaze AEX Hybrid Purifier in the clarification stage can improve product purity and yield early in the process and may reduce the total cost of ownership for the mAb purification process.

One product performing **multiple** actions



3M™ Emphaze™ AEX Hybrid Purifier for Monoclonal Antibody Processing

In a representative monoclonal antibody (mAb) manufacturing process, when used in combination at the clarification stage with a depth filter and membrane filters, the 3M Emphaze AEX Hybrid Purifier increases process efficiency and protein purity post Protein A.



Impact of 3M™ Emphaze™ AEX Hybrid Purifier on Clarification step and Protein A performance

- 10X less HCP post-Protein A
- 1,000X DNA reduction post-Protein A
- 10X less residual contaminants on Protein A column
- Significant reduction in filter surface area of sterilizing filters
- Consistent output turbidity (<5 NTU)
- Nominal 20-40% HCP reduction pre-Protein A

Figure 1: HCP concentrations in CHO harvest or centrate (1), clarified fluid (2), protein A eluate (3), and clean-in-place fluid (4) when CHO harvest/ centrate was clarified using either 3M Depth Filtration Clarification (grey) or 3M™ Emphaze™ AEX Hybrid Purifier (orange).

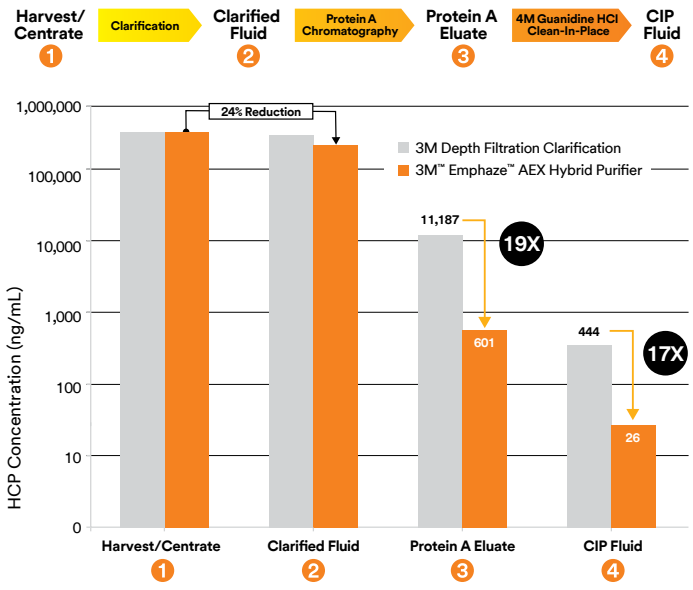
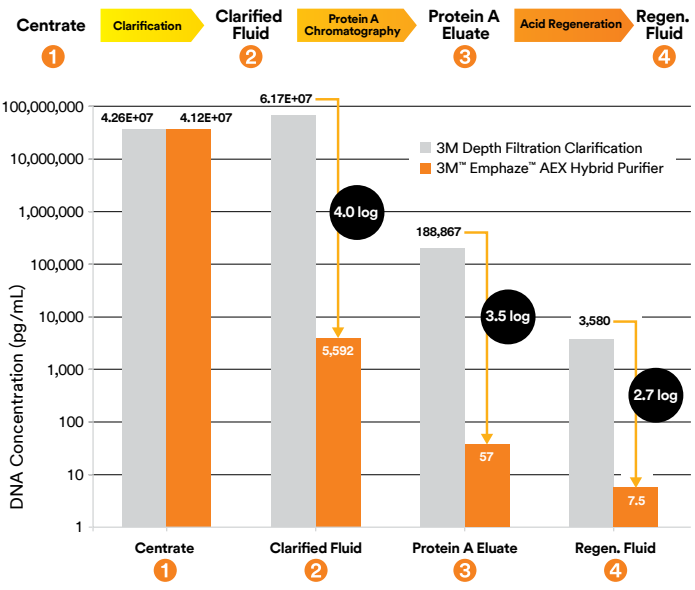


Figure 2: DNA concentrations in CHO centrate (1), clarified fluid (2), protein A eluate (3), and acid regeneration fluid (4) when CHO centrate was clarified using either 3M Depth Filtration Clarification (grey) or 3M™ Emphaze™ AEX Hybrid Purifier (orange).



Reference: 3M Tech Note 01 - Performance of 3M™ Emphaze™ AEX Hybrid Purifier in monoclonal antibody (mAb) purification process.

Excellent contaminant reduction coupled with Protein A chromatography

Figure 3: HCP concentration in Protein A eluate over multiple chromatography cycles

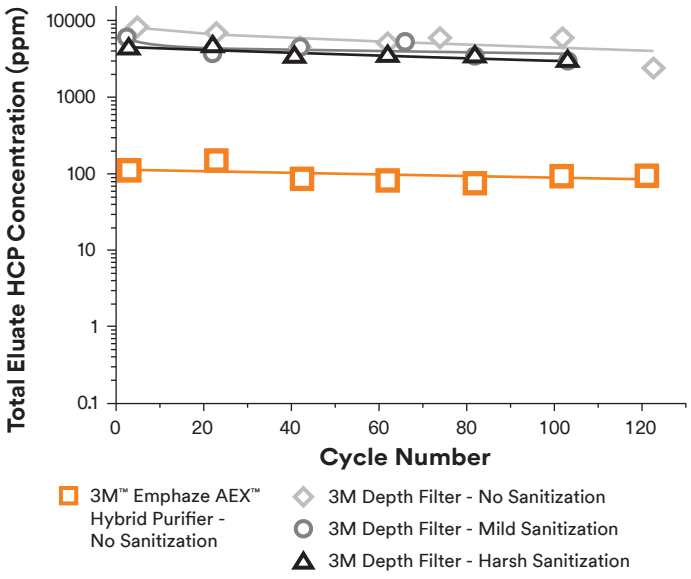
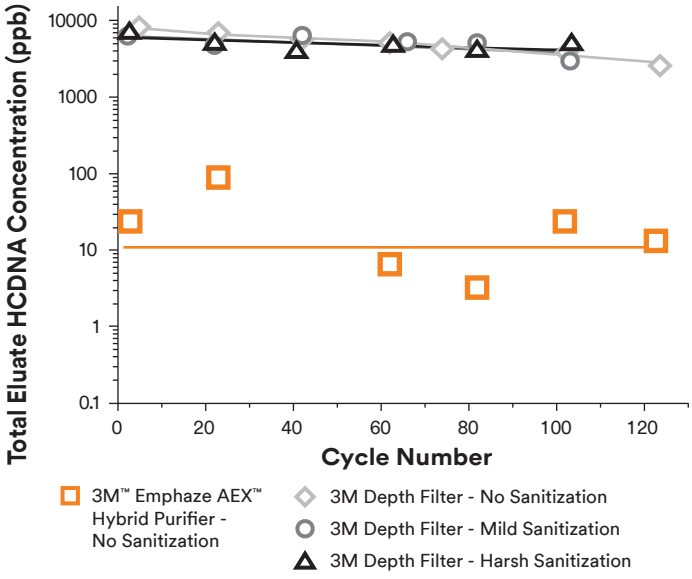
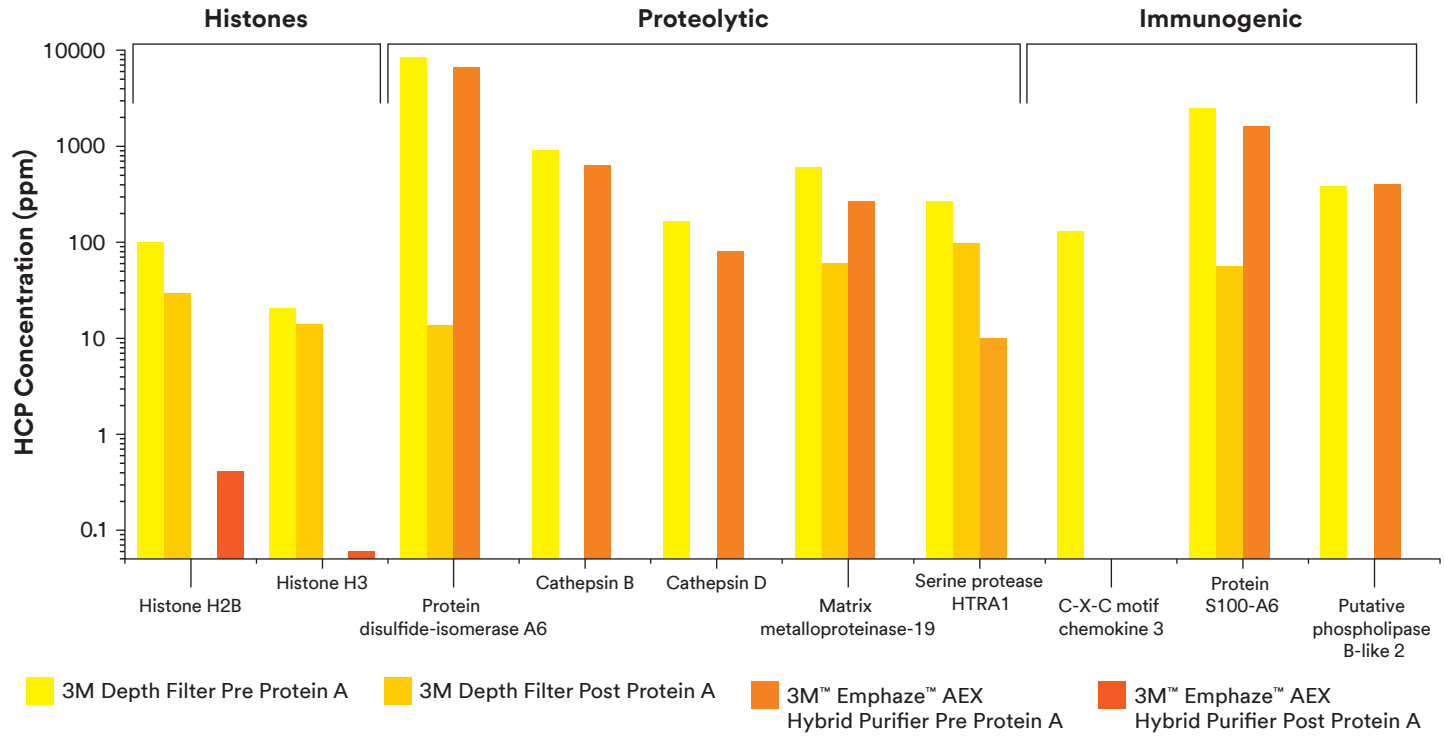


Figure 4: DNA concentration in Protein A eluate over multiple chromatography cycles



Problematic host cell protein reduction pre- and post-Protein A

Figure 5: Removal of selected problematic HCPs during primary clarification through Protein A chromatography



Reference: Modified from Gilgunn et al. 2019. Identification and tracking of problematic host cell proteins removed by synthetic, highly functionalized nonwoven media in downstream bioprocessing of monoclonal antibodies. Journal of Chromatography A. DOI: 10.1016/j.chroma.2019.02.056

Bacterial Lysate Processing

In a representative bacterial lysate process, a decrease of soluble contaminants and increase of process robustness may be achieved by using 3M™ Emphaze™ AEX Hybrid Purifier.

High Performance Clarification Process

- Endotoxin reduction
- DNA reduction
- HCP reduction

Impact Downstream of Clarification

- Reduced impurities may lead to chromatography column protection (e.g. IMAC, CEX)

Figure 6: Representative process for clarification and purification of products from bacterial lysate.

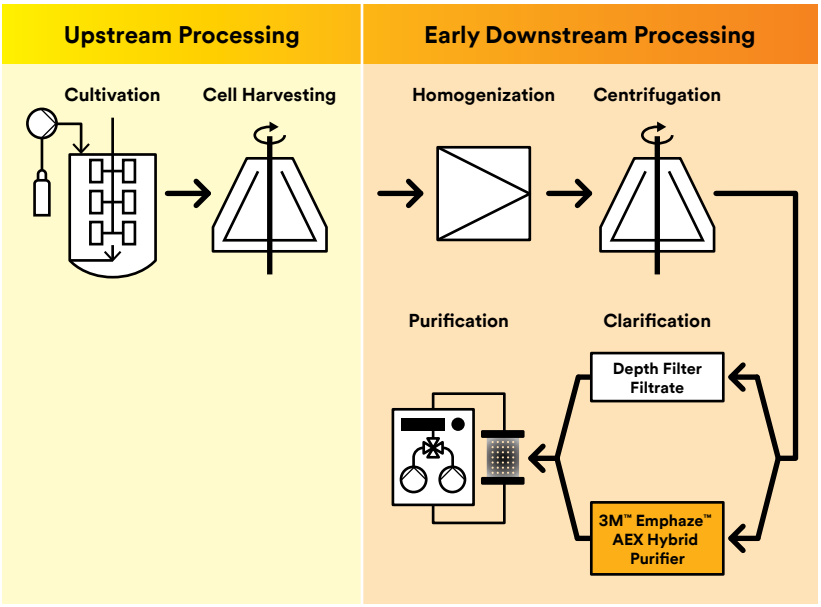
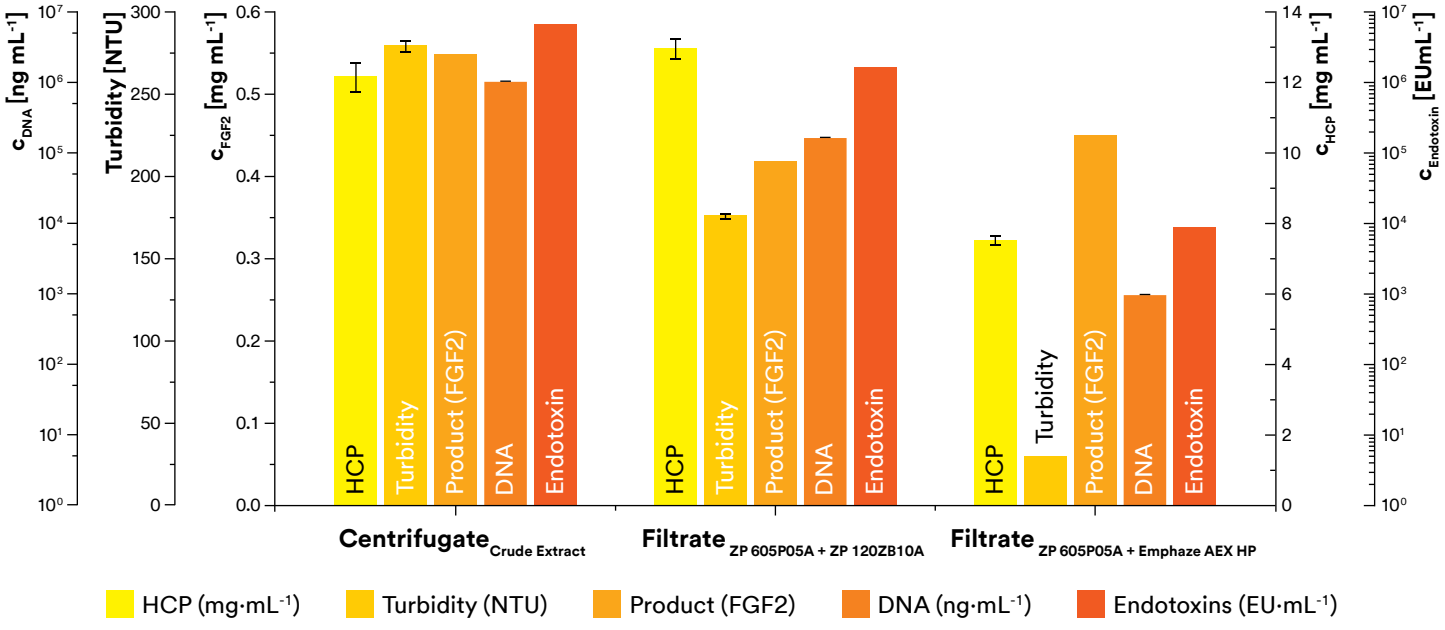


Figure 7: Proof-of-concept: comparison of a conventional depth filtration and an adsorptive filtration. (a) Analyte/impurity concentration comparison of the crude pool against depth filter filtrate and an adsorptively clarified filtrate.

(a)



Reference: Modified from Metzger et al. 2019. Adsorptive filtration: A case study for early impurity reduction in an *Escherichia coli* production process. Biotechnology Progress. DOI: 10.1002/btpr.2948

Laboratory, pilot, and production capsules

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
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 × 7.7 cm (1.7 × 3.0 in.)	8.8 × 7.7 cm (3.5 × 3.0 in.)	10.3 x 21.6 cm (4.1 × 6.5 in.)		15.2 × 21.6 cm (6.0 × 6.5 in.)	5.7 × 45.2 cm (2.2 × 17.8 in.)	20.3 × 45.2 cm (8.0 × 17.8 in.)
Dry Weight		9.0 g	14.5 g	71 g	77 g	1.0 kg	1.1 kg	1.6 kg	3.4 kg	9.5 kg
Weight Wet Post Blow Down		9.5 g	16.0 g	80 g	85 g	1.1 kg	1.2 kg	2.1 kg	4.1 kg	14.2 kg
Fill Volume[1]		2.0 mL	5.5 mL	13 mL	16 mL	0.55 L	0.55 L	1.4 L	3.4 L	10.6 L
Hold up Volume Post Blow Down[2]		0.5 mL	1.5 mL	9 mL	9 mL	0.10 L	0.15 L	0.46 L	0.70 L	4.7 L
Capsule Material		Polypropylene		Polypropylene, Glass Filled Polypropylene		Polypropylene, Glass Filled Polypropylene, Polysulfone, Fluorocarbon			Polypropylene, Glass Filled Polypropylene, Glass Filled Polyphenylene 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	130 mL		0.9 L	1.8 L	5.5 L	12 L	85 L
Recommended Use Flow Rate		0.4 mL/min	1.4 mL/min	8 mL/min		50 mL/min	100 mL/min	300 mL/min	680 mL/min	4700 mL/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 70C minimum. 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.

Additional References and Literature

- 3M Tech Note 01 - Performance of 3M™ Emphaze™ AEX Hybrid Purifier in monoclonal antibody (mAb) process in mammalian cell cultures
- 3M Application Note 02 - Endotoxin removal by 3M™ Emphaze™ AEX Hybrid Purifier
- 3M Tech Note 01 - Identification and tracking of problematic host cell proteins when using 3M™ Emphaze™ AEX Hybrid Purifier in mAb manufacturing processes
- 3M Application Note 01 - Quantification of 3M™ Emphaze™ AEX Hybrid Purifier value in mAb manufacturing process

- Maurer et al. 2014. Advanced clarification of cell culture supernatant by 3M™ Emphaze™ AEX Hybrid Purifier for fast and economic bioprocessing of recombinant proteins. DOI: 10.1016/j.nbt.2014.05.1897
- Singh et al. 2017. Development of adsorptive hybrid filters to enable two-step purification of biologics. MAbs. DOI: 10.1080/19420862.2016.1267091
- El-Sabbahy et al. 2018. The effect of feed quality due to clarification strategy on the design and performance of protein A periodic counter-current chromatography. Biotechnology Progress. DOI: 10.1002/btpr.2709
- Koehler et al. 2019. Enhancing Protein A performance in mAb processing: A method to reduce and rapidly evaluate host cell DNA levels during primary clarification. Biotechnology Progress. DOI: 10.1002/btpr.2882
- Gilgunn et al. 2019. Identification and tracking of problematic host cell proteins removed by a synthetic, highly functionalized nonwoven media in downstream bioprocessing of monoclonal antibodies. Journal of Chromatography A. DOI: 10.1016/j.chroma.2019.02.056
- Metzger et al. 2019. Adsorptive filtration: A case study for early impurity reduction in an Escherichia coli production process. Biotechnology Progress. DOI: 10.1002/btpr.2948
- Pinto et al. 2020. Impact of micro and macroporous TFF membranes on product sieving and chromatography loading for perfusion cell culture. Biotechnol Bioeng. DOI: 10.1002/bit.27192
- Van de Velde et al. 2020. Chromatographic clarification overcomes chromatin-mediated hitch-hiking interactions on Protein A capture column. Biotech Bioeng. DOI: 10.1002/bit.27513
- Metzger et al. 2020. IGF1 inclusion bodies: A QbD based process approach for efficient USP as well as early DSP unit operations. Journal of Biotechnology. DOI: 10.1016/j.jbiotec.2020.02.014
- Meingast et al. 2021. Physiochemical properties of enveloped viruses and arginine dictate inactivation. Biotechnology Journal. DOI: 10.1002/biot.202000342
- Holstein et al. 2021. Control of leached beta-glucan levels from depth filters by an improved depth filtration flush strategy. Biotechnology Progress. DOI: 10.1002/btpr.3086

For more information about the 3M™ Emphaze™ AEX Hybrid Purifier, contact your local sales rep by calling 1800-425-3030, or visit us at www.3mindia.in/3M/en_IN/bioprocessing-in/

Intended Use Statement: 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.

Restrictions on 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 Regulation (MDR), 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.

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 safety, conducting a workplace hazard assessment and reviewing all applicable regulations and standards. 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: Unless a different warranty is expressly identified on the applicable 3M product literature or packaging (in which case such express warranty governs), 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 A PARTICULAR PURPOSE, OR ARISING OUT OF A COURSE OF DEALING, CUSTOM, OR USAGE OF TRADE. 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.

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