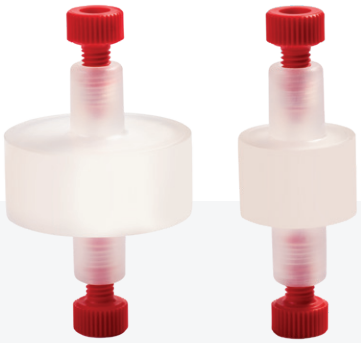
GORE® Protein Capture Device with Protein A

For Drug Discovery Applications

HIGH BINDING CAPACITY AND SHORT RESIDENCE TIME FOR THE RAPID PURIFICATION OF mAbs



GORE Protein Capture Devices with immobilized Protein A are intended for affinity purification of monoclonal antibodies in drug discovery applications. The Devices are offered in 1.0 mL and 3.5 mL and use a unique expanded polytetrafluoroethylene (ePTFE) membrane composite that provides a binding capacity advantage at high flow rates and improves the speed of purification.

In addition, the Devices produce highly concentrated elution pools, which may eliminate a downstream concentration step during the antibody purification process.

Common Applications

Affinity purification and screening of mononclonal antibodies in drug discovery applications and production of antibodies for research and development.

Improved Performance

This pre-packed column provides performance benefits without causing collapse, channeling or alteration of the membrane bed. The unique ePTFE membrane bed provides high capacity at short residence time and is durable to repeated cleaning cycles.

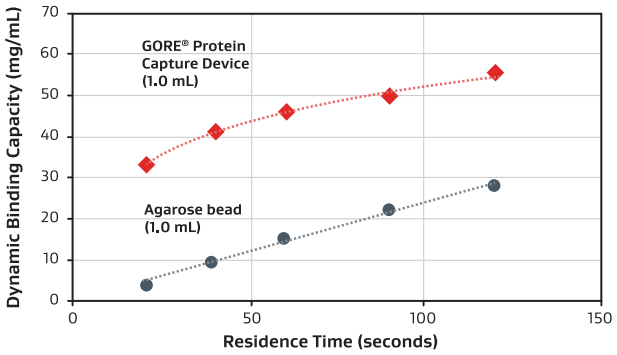


Figure 1. Typical dynamic binding capacity of the GORE Devices versus a standard agarose bead based technology. The difference between Performance Data (back page) and this DBC curve (above) curve reflects different techniques to assess overall binding capacity.

Key Features and Benefits

Key features

- High dynamic binding capacity (≥30 mg/mL)
- Short residence time (20 seconds)
- Stable ePTFE membrane bed
- Durable to repeated cleaning cycles
- Pre-packed column

Key benefits

- Improved throughput and productivity
- Increased concentration of antibody in the elution pool
- Potential to eliminate downstream concentration step
- Reduced set-up time

Regulatory Compliance

GORE Protein Capture Devices are manufactured following the applicable material quality and regulatory requirements. Contact Gore for current applicable compliance statements.

Quality Statement

The Devices are manufactured in a manner that adheres to relevant Good Manufacturing Practices as defined in the Gore PharmBIO Products' quality system which is certified to ISO 13485.

Intended Use

GORE Protein Capture Devices are intended for research use only and should not be used for clinical or diagnostic procedures.

Together, improving life

Performance Data

Characteristic	Antibody Purification Device*		
	GORE Device (1.0 mL)		Agarose bead 1.0 mL device
	(Initial)	(Post 20th cycle)	
	20 seconds residence time		60 seconds residence time
Average DBC (mg/mL)**	39.4 ± 2.2	36.5 ± 1.7	21.3
Protein A leaching (ppm)	5.96 ± 1.74	3.77 ± 1.05	2.2 ± 0.9
Yield (%)	101.4 ± 4.2	101 ± 3.4	96.9 ± 3.6
HCP (ppm)****	1010 ± 371	1155 ± 281	765 ± 306
Ligand stability	0.1 N NaOH (maximum)		0.1 N to 0.5 N NaOH***
Maximum operating pressure	5 bar		5 bar

* Gore Devices represent mean of 12 devices per size
** Determined using polyclonal human IgG at 10% breakthrough.
*** Agarose bead technology has stability to 0.5N NaOH; the user should refer to instructions for use for specific information
**** From CHO cell harvest.
DBC – dynamic binding capacity; HCP – host cell protein; NaOH – sodium hydroxide; ppm – parts per million

Data for the 3.5 mL device is available in the GORE Protein Capture Device Validation Guide.

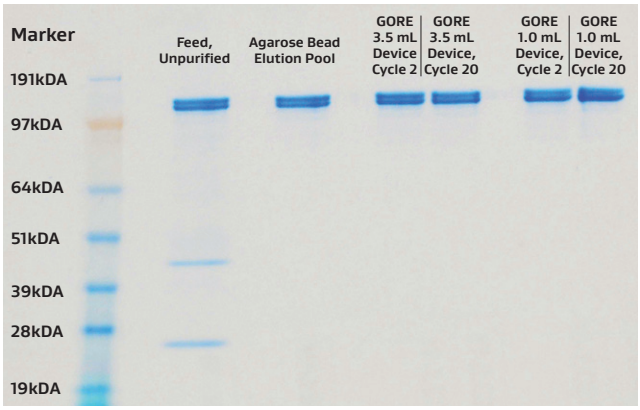


Figure 2. SDS-PAGE of eluent recovered from the GORE Device versus a standard agarose bead-based technology. GORE Device residence time 20 seconds; competitor device 60 seconds. The purity of the eluents recovered from both purification devices was similar. Therefore, a short residence time did not negatively affect the purity of the antibody eluted from the GORE Device.

Part number/Ordering Information

Part Number	Description	Quantity
PROA101	1.0 mL Device	1/box
PROA102	3.5 mL Device	1/box

Technology

Unlike traditional support matrices, the membrane bed in the Device provides a near linear pressure drop at a wide range of flow rates (Figure 3).

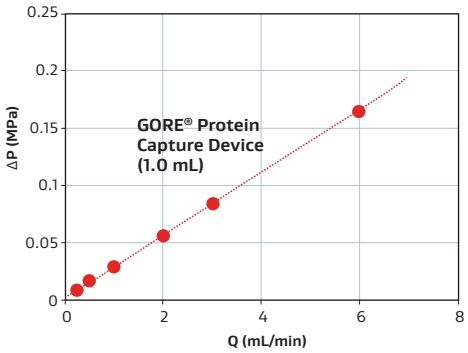


Figure 3. Column pressure drop (Δ) of GORE Device (1.0 mL) at various flow rates.

Operating conditions

The typical flow rate at a residence time of 20 seconds is 3 mL/min for the 1.0 mL Device and 10.5 mL/min for the 3.5 mL Device. Refer to the *GORE Protein Capture Device for Drug Discovery Operating Instructions (1.0 mL and 3.5 mL)* for more detailed information.

Packaging/Storage information

Store the Device in the refrigerator at 2–8°C (35– 46°F), in 20% ethanol solution in deionized water. Device has one year shelf life as determined by accelerated aging tests. Refer to the Operating Instructions for detailed operating and handling guidelines.

Device Characteristics

Description	Material/Characteristic
Column, flow distributors, frits, and plugs	Polypropylene
Membrane bed	Expanded polytetrafluoroethylene (ePTFE) composite
Protein A	Recombinant Protein A from *Staphylococcus aureus*
Connectors	10-32 threaded fittings

Gore PharmBIO Products

Our technologies, capabilities, and competencies in fluoropolymer science are focused on satisfying the evolving product, regulatory, and quality needs of pharmaceutical and bioprocessing customers, and medical device manufacturers. GORE Protein Capture Devices with Protein A, like all products in the Gore PharmBIO Products portfolio, are tested and manufactured under stringent quality systems. These high-performance products provide creative solutions to our customers' design, manufacturing, and performance-in-use needs

NOT INTENDED FOR USE in medical device or food contact applications or with radiation sterilization.

All technical information and advice given here is based on our previous experiences and/or test results. We give this information to the best of our knowledge, but assume no legal responsibility. Customers are asked to check the suitability and usability of our products in the specific applications, since the performance of the product can only be judged when all necessary operating data is available. Gore's terms and conditions of sales apply to the purchase and sale of the product.

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