GORE® Protein Capture Device with Protein A, 9.0 mL

For Process Development, Pre-Clinical, and Early Clinical Applications

HIGH BINDING CAPACITY AND SHORT RESIDENCE TIME FOR HIGH-PRODUCTIVITY ANTIBODY PURIFICATION

GORE Protein Capture Devices, 9.0 mL with Protein A are intended for the affinity purification of monoclonal antibodies from clarified harvest streams in process development, pre-clinical and early clinical applications. The devices use a unique expanded polytetrafluoroethylene (ePTFE) membrane composite that provides a binding capacity advantage at high flow rates and improves the speed of purification over traditional technologies (FIGURE 1).

Unlike traditional support matrices, the membrane bed in the GORE Protein Capture Device provides a linear relationship between pressure drop and a wide range of flow rates without causing collapse, channeling or alteration of the membrane bed (FIGURE 2).

Figure 1. Representative dynamic binding capacity of GORE Protein Capture Device versus a standard agarose bead-based technology using a purified monoclonal antibody

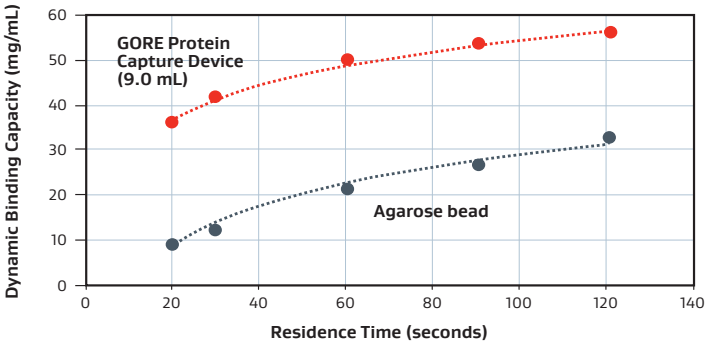
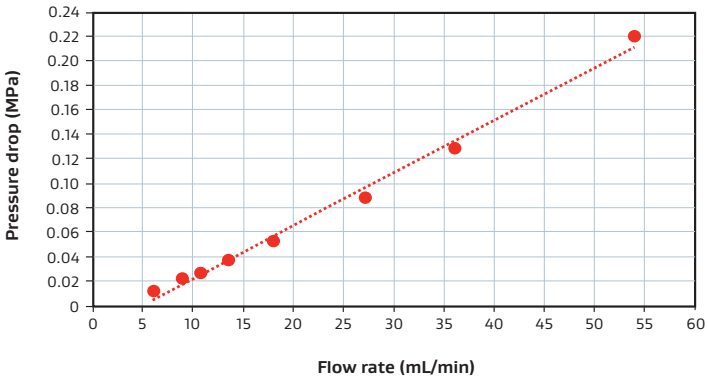


Figure 2. Example pressure drop vs. flow rate relationship for the GORE Device when using phosphate buffer at room temperature



Key Features and Benefits

Key features

- High dynamic binding capacity (≥40 mg/mL; initial)
- Short residence time (30 seconds)
- Stable membrane bed
- Demonstrated ability to cycle 100 times with cleaning
- Compatible with standard chromatography systems
- Pre-packed column

Key benefits

- Improved throughput and productivity
- Potential increased concentration of antibody in the elution pool

Together, improving life

Performance Data

Performance evaluations were performed with CHO clarified cell culture harvest trastuzumab biosimilar. Clarified CHO cell harvest (CCH) had a titer of 3.93 g/L. The extracts were clarified and filtered through a 0.2 µm filter prior to loading.

For purification, the Device was loaded to 80% of its 40 mg/mL capacity. Loading and acid strip were performed at 18 mL/min at 30 seconds residence time (SRT), equilibration, elution, and washes were run at 27 mL/min (20 SRT), and CIP was run at 10.8 mL/min (50 SRT).

Two Devices were tested with CCH.

Characteristic	Averages of Cycles 1, 25, 50, 75 and 100
*Initial DBC (n=28)	48.5
Protein A leaching (ppm)	1.54**
Yield (%)	90.5
HCP (ppm)***	677.72
HCP LRV	2.1
Elution Width (CV)	1.83
CIP	0.2N NaOH at 10.8mL/min for 3 minutes every cycle
Maximum Operation Pressure	<0.4MPa

DBC- dynamic binding capacity; HCP- host cell protein; NaOH- sodium hydroxide; ppm-parts per million.

* Determined using polyclonal human IgG (1.25g/L) at 10% breakthrough and a residence time of 30 sec.

**Represent average Protein A leaching values for cycles 1, 25, 50, 75 and 100 of two separate devices. The initial cycle was included in the average

***Cycle 1 and Cycle 100 measurement only.

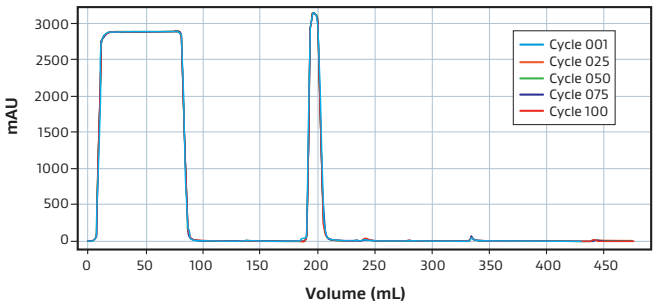
Operating conditions

The GORE Device is typically operated between 20 SRT (27 mL/min) and 30 SRT (18 mL/min). Refer to the *9.0 mL GORE Protein Capture Device Operating Instructions* for more detailed information.

Packaging/Storage information

Store Device at 2–8°C (35.6– 46.4°F), filled with 20% ethanol / 80% deionized water. Device has three year shelf life as determined by accelerated aging tests. Refer to the *GORE Protein Capture Device Operating Instructions* for detailed operating and handling guidelines.

Figure 3. Typical chromatogram showing cycles 1, 50, and 100 overlaid for GORE Protein Capture Device



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

GORE Protein Capture 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, and ISO 15378.

Device Characteristics

Component	**Material of Construction**
Column housing components	Polypropylene
Membrane	Expanded polytetrafluoroethylene (ePTFE) composite
Protein A	Recombinant Protein A from *Staphylococcus aureus*
Connectors	10-32 coned thread port
End plugs	Polyetheretherketone (PEEK)

Part number/Ordering Information

Part Number	**Description**	**Quantity**
PROA103	9.0 mL Device	1/box

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.

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