ХРОМАТОГРАФИЧЕСКИЕ СРЕДЫ PROSEP

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Introduction

The ProSep-A family of protein A affinity media include:

ProSep-vA Ultra media	Vegan native protein A immobilized on 700 Å Controlled Pore Glass
ProSep-vA High Capacity media	Vegan native protein A immobilized on 1000 Å Controlled Pore Glass
ProSep-A High Capacity media	Native protein A immobilized on 1000 Å Controlled Pore Glass
ProSep-rA High Capacity media	Recombinant protein A immobilized on 1000 Å Controlled Pore Glass

ProSep-A affinity adsorbents have been developed to facilitate highly efficient, cost effective purification of both monoclonal and polyclonal antibodies. ProSep-vA Ultra media and ProSep-vA High Capacity media are manufactured using no mammalian products.

ProSep-A media consist of protein A immobilized on porous glass which is permeated by interconnecting pores of uniform and precisely controlled size. ProSep-A exhibits chemical and mechanical stability over a range of conditions such as low pH, exposure to detergents, buffers of varying ionic strengths, and many organic solvents. ProSep-A media are incompressible, extremely durable, and do not shrink or swell in different solutions. They have a narrow pore size distribution (80% of the pores show a deviation of less than ±10% from the nominal pore diameter) coupled with a large internal surface area.

Proprietary chemistry is used for the immobilization of protein A onto the controlled pore glass and has been developed to satisfy four critical factors:

- orientation of the ligand
- distribution of the ligand
- stability of the immobilized ligand
- minimization of nonspecific surface interactions

The combination of these factors means that ProSep A media are ideally suited for the efficient, cost effective and rapid purification of antibodies directly from clarified bioreactor feedstock, particularly for large scale industrial use.

ProSep-vA Ultra media, the result of an extensive development program, retains the same basic attributes of ProSep-vA High Capacity media and provides even higher binding capacity. It is specifically designed to provide high productivity and low cost of operation for today's large volume, higher titer feedstocks.

Intended Use

The ProSep-A family of media may be used for applications including:

- purification of monoclonal antibodies (MAbs)
- purification of fusion proteins
- selective purification of antibody fragments
- purification or removal of polyclonal IgG from serum
- separation of IgG subclasses using a stepwise pH gradient

ProSep-A affinity media have been developed specifically for industrial scale purification of monoclonal antibodies where highly efficient purification can be achieved using clarified bioreactor feedstock at physiological pH and salt concentration. No pretreatment such as concentration by ultrafiltration or buffer exchange to increase salt concentration and capacity is required. This reduces time, labor and capital cost and improves retention of biological integrity of the antibody product.

In some cases ProSep A media may also be used to purify antibody fragments (for example, see Kelley et al, 1992).

ProSep-vA Ultra media or ProSep-vA High Capacity media?

ProSep-vA Ultra media with its 700 Å pore size and high surface area provides the best combination of capacity and throughput for most antibodies with a molecular weight in the region of 150kD (IgG's). For fusion proteins or conjugates where the actual or effective molecular weight is larger than 150kD, the 1000 Å based ProSep-vA High Capacity media may result in higher dynamic capacity due to the larger pore diameter which provides less hindered mass transfer for the larger molecule.

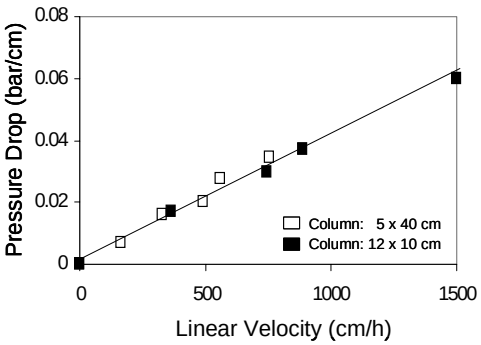
Typical Specifications

Matrix	Porous glass
Particle size	75 - 125 µm
Pore Size	700 Å, ProSep-vA Ultra media 1000 Å, ProSep-vA High Capacity media ProSep-A High Capacity media ProSep-rA High Capacity media
pH range	pH 1 to 9
Pressure	Incompressible matrix with linear pressure/flow rate characteristics.
Maximum operating pressure	< 3000 psi (200 bar)
Packed Bed Density	1.3 g/mL
Life	ProSep-A media are stable over repeated operational cycles when proper cleaning protocols are used.
Protein A Ligand	Native protein A from *Staphylococcus aureus,* ProSep-vA Ultra media, ProSep-vA High Capacity media, ProSep-A High Capacity media Recombinant protein A expressed in *E. coli,* ProSep-rA High Capacity media
Binding (Static) Capacity	ProSep-vA/A/rA High Capacity media Human IgG > 40mg/mL Bovine 27 mg/mL Goat 17 mg/mL Mouse 33 mg/mL Porcine 38 mg/mL Rabbit 37 mg/mL Rat 13 mg/mL Sheep 13 mg/mL ProSep-vA Ultra media Human IgG Static Capacity > 56 mg/mL Typical dynamic capacity for humanized monoclonal antibodies ranges from 15-30 mg/mL for ProSep-vA/A/rA High Capacity media and 20-45 mg/mL for ProSep-vA Ultra media.

Pressure Drop and Flow Rate

The particle size range and rigid nature of ProSep-A media mean that pressure drop, even at high flow rates is low and that pressure/flow data exhibit a linear relationship irrespective of column diameter. This ensures that scale-up is straightforward and predictable, even when moving to very large production columns over 1 meter diameter.

The low inherent pressure drop enables high flow rates and/or longer bed lengths to be utilized, increasing flexibility in process design. The predicted pressure drop can be calculated using the following equation.



$$\Delta P(bar)/L(cm) = 4x10^{-5} \times V\ (cm/hr)$$

Ordering Information

	Catalogue Number			
Quantity	ProSep-vA Ultra Media	ProSep-vA High Capacity Media	PROSEP-A High Capacity Media	PROSEP-rA High Capacity Media
2 mL pre-packed column	N/A	N/A	113111522	113112522
2 mL	115115822	113115822	113111822	11311722
10 mL	115115824	113115824	113111824	11311724
50 mL	115115826	113115826	113111826	11311726
100 mL	115115827	113115827	113111827	11311727
500 mL	115115829	113115829	113111829	11311729
1 L	115115830	113115830	113111830	11311730
5 L	115115833	113115833	113111833	11311733
10 L	115115835	113115835	113111835	11311735

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