

ХРОМАТОГРАФИЧЕСКИЕ СРЕДЫ PROSEP ULTRA PLUS



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ProSep® Ultra Plus Chromatography Media

The highest dynamic binding capacity Protein A affinity chromatography media, designed for cost-effective, large-scale purification of today's higher titer therapeutic antibodies.

ProSep® Ultra Plus media is a Protein A-based affinity resin with the highest dynamic binding capacity and flow rate capability of any comparable resin on the market. Based on the proven technology of ProSep® media, ProSep® Ultra Plus media provides increased capacity and productivity compared to competing resin-based technologies.

Benefits

- Highest capacity
- Proven technology
- High throughput for maximum productivity
- Reliable scale-up
- Lower cost of operation

Proven Technology

ProSep® Ultra Plus media has been developed from ProSep®-vA media, which is used extensively in the manufacture of today's approved therapeutic monoclonal antibodies. ProSep® Ultra Plus media is the result of extensive investigation into optimizing ProSep® media to address the developing needs of the industry.

Utilizing smaller CPG® particles, together with refinement of pore size selection and ligand immobilization, has enabled the significant increase in dynamic capacity.

The open, interconnected pore structure maintains rapid mass transfer, resulting in these higher dynamic capacities being achievable over a wide range of flow rates or residence times (see Figure 1).

As a result of the open pore structure and outstanding mass transfer characteristics (see Figure 2), the sharp breakthrough curves permit higher loading percentages to be utilized before risk of premature breakthrough, thereby maximizing column capacity.

Operational Flexibility

The porous glass base matrix is fully incompressible, leading to a linear relationship between back pressure and flow rate. The response of a ProSep® Ultra Plus media packed column to increased flow rate is therefore entirely predictable over different column lengths and diameters. Although a smaller particle size is utilized in ProSep® Ultra Plus media, the combination of total rigidity and particle size still allows operation at flow rates of 500 cm/h if desired. This relationship is illustrated in Figure 3 with data generated using columns of different diameters.



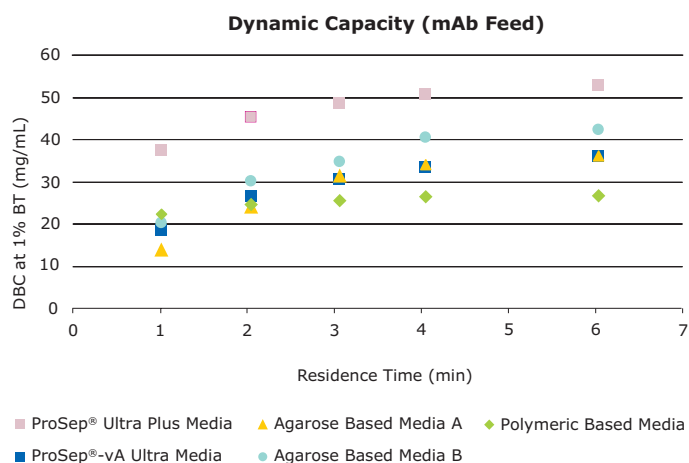


Figure 1.
Dynamic capacity of ProSep® Ultra Plus media compared with competitive media.

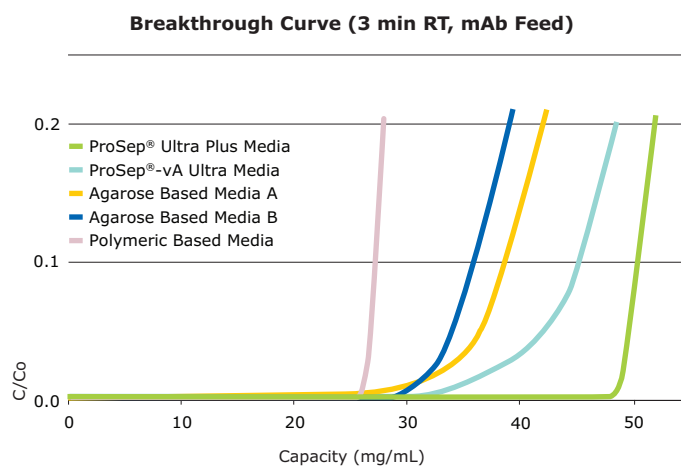


Figure 2.
Breakthrough curves for ProSep® Ultra Plus media compared with competitive media.



Large-scale column (1.6 m) packed with ProSep® media.

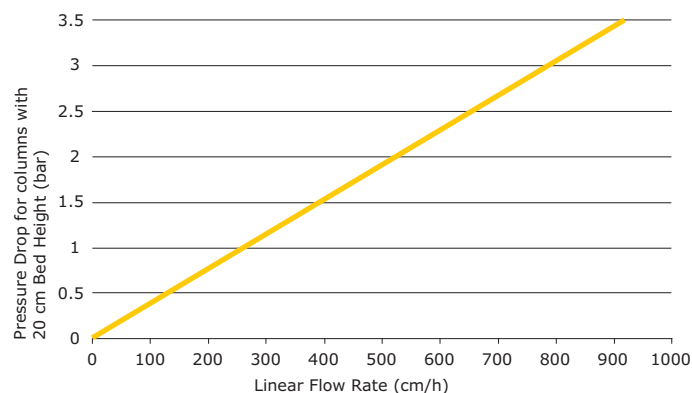


Figure 3.
Response of ProSep® Ultra Plus media to increased flow rate.

Storage and Handling

ProSep® Ultra Plus media is supplied in 0.1M acetate buffer, pH 5.2 and 1% benzyl alcohol as a preservative.

During use, it is recommended to store ProSep® Ultra Plus media in 0.1M acetate buffer, pH 5.2 containing 1% or 2% benzyl alcohol as a preservative. Alternatively, ProSep® Ultra Plus media may be stored in phosphate-buffered saline (PBS) or other suitable buffer containing a preservative. The acceptable environmental storage temperature for ProSep® Ultra Plus media is between 2 – 8°C.

ProSep® Ultra Plus Prepacked Column Specifications

Components	Column – Polypropylene (PP) Bed Supports – 17 µm Polypropylene/ Polyethylene (PP/PE)
Connections of the MiniChrom Columns	10 – 32 UNF 1/16 in. fingertight, PEEK or PTFE Capillaries 1/16 in. (o.d.) with 0.5 – 0.8 mm (i.d).
Column Geometries/Volumes	8 mm (i.d.) x 20 mm 1.0 mL 8 mm (i.d.) x 100 mm 5.0 mL
Maximum Back Pressure	20 bar
Chemical Stability	Columns are tolerant to aqueous buffers and salt solutions, 8M urea, 6M guanidine hydrochloride, organic solvents and detergents.
Temperature Range	4 – 30°C
Storage	2 – 8°C

ProSep® Ultra Plus Media Characteristics

Base Matrix	Controlled Pore Glass
Particle Size	60 µm
Ligand	Recombinant native Protein A
Binding Capacity – Static	Typically ≥ 67 mg/mL (hIgG)
Binding Capacity – Dynamic	Typically >50 mg/mL (10% breakthrough at 3 – 6 min residence time)
Recommended Mobile Phase Velocity	Up to 500 cm/hr
Recommended Bed Height	20 cm
Recommended Long-Term Storage	2 – 8°C, plus bacteriostat

Manufacturing Standards and Quality Assurance

We recognize the importance of providing regulatory support and meeting industry quality standards. ProSep® Ultra Plus media utilizes recombinant native protein A derived from *E. coli*. No mammalian-derived materials are used to manufacture ProSep® Ultra Plus media and its components. All ProSep® media products are manufactured in a facility certified to internationally recognized standard ISO® 9001 and subjected to routine independent surveillance audits.



Ordering Information

Media*	Qty/Pk	Catalogue No.
ProSep® Ultra Plus Media	2 mL	175118822
ProSep® Ultra Plus Media	10 mL	175118824
ProSep® Ultra Plus Media	100 mL	175118827
ProSep® Ultra Plus Media	1 L	175118830
ProSep® Ultra Plus Media	5 L	175118833
ProSep® Ultra Plus Media	10 L	175118835
ProSep® Ultra Plus Media	25 L	175118834

*Supplied as 50% slurry in 0.1M acetate buffer, pH 5.2, 1% benzyl alcohol.

Media*	Qty/Pk	Catalogue No.
MiniChrom Column	1 mL	1.25067.0001
MiniChrom Column	5 mL	1.25076.0001
RoboColumn® Column	0.2 mL	1.25135.0001
RoboColumn® Column	0.6 mL	1.25143.0001

*Supplied in 0.1M acetate buffer, pH 5.2, 1% benzyl alcohol.

Description	Catalogue No.
Buffer Preparation	
Phosphoric acid 75% suitable for biopharmaceutical production	100250
di-Potassium hydrogen phosphate anhydrous suitable for biopharmaceutical production EMPROVE® bio Ph Eur, BP, USP	137010
Sodium chloride suitable for biopharmaceutical production EMPROVE® bio Ph Eur, BP, JP, USP	137017
Sodium dihydrogen phosphate dehydrate suitable for biopharmaceutical production EMPROVE® bio Ph Eur, BP, USP, JPE	137018
Sodium hydroxide pellets suitable for biopharmaceutical production EMPROVE® bio Ph Eur, BP, JP, NF, ACS	137020
Sodium hydroxide solution 1 mol/L suitable for biopharmaceutical production EMPROVE® bio	137031
Tris(hydroxymethyl)aminomethane (Trometamol) TRIS suitable for use as excipient EMPROVE® exp Ph Eur, BP, USP	108386
Tris(hydroxymethyl)aminomethane (Trometamol) TRIS high purity suitable for biopharmaceutical production EMPROVE® bio Ph Eur, BP, JPC, USP, ACS	108307
Tris(hydroxymethyl)aminomethane hydrochloride TRIS-HCl suitable for biopharmaceutical production EMPROVE® bio	108219

Description	Catalogue No.
Column Cleaning & Storage of ProSep® Resins	
Acetic acid 1 mol/L suitable for biopharmaceutical production EMPROVE® bio	137035
Acetic acid 30% suitable for biopharmaceutical production EMPROVE® bio Ph Helv	137047
L-Arginine suitable for use as excipient EMPROVE® exp Ph Eur, USP	101587
Benzyl alcohol suitable for biopharmaceutical production EMPROVE® bio Ph Eur, BP, JP, NF, ACS	137043
Ortho-Phosphoric acid 75% suitable for biopharmaceutical production	100250
PAB	480949

Recommended ELISA Kit	Catalogue No.
ELISA Kit for the Detection of Native and Recombinant Protein A*	9000-1

*This product can be purchased directly from Repligen Corp.



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