

# CHROMATOGRAPHY

## Nuvia™ HR-S Cation Exchange Media

- Best-in-class resolution
- High recovery of target biomolecules
- Robust polymeric matrix
- Scalable to industrial purification applications
- Full regulatory support

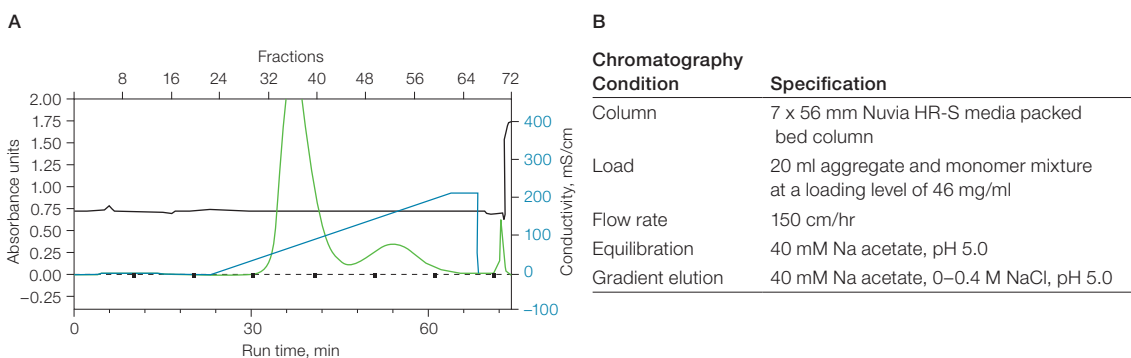
### Exceptional Resolution of Closely Related Species for Process Purification

#### Introduction

Nuvia HR-S media is a strong cation exchanger, optimized for particle size and chemistry, that provides exceptional resolution and high recovery. The media is built on Bio-Rad's commercially proven UNOsphere™ base bead that demonstrates fast mass transfer kinetics, excellent flow characteristics, and robust chemical stability against common caustic cleaning protocols. Its excellent scalability gives process developers the confidence that results obtained on the bench will be reproducible for large-scale downstream manufacturing. Nuvia HR-S media is the preferred solution for intermediate and final polish applications where process developers face challenging separations of closely related biomolecules.

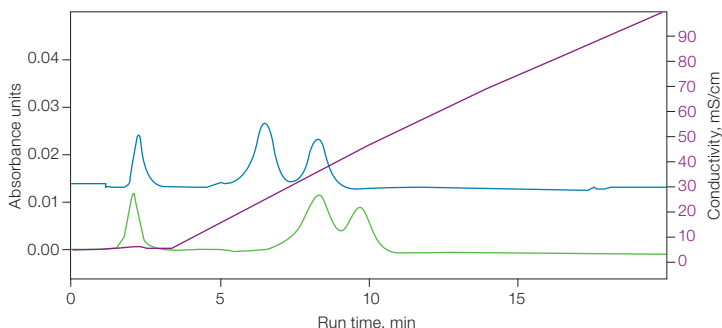
#### High Resolution

Improvements in upstream cell culture expression systems have produced high feed stream titers that place a larger demand on downstream purifications to separate closely related contaminants from target biomolecules. In monoclonal antibody therapeutics, high molecular weight impurities in the form of aggregates are a key challenge for process developers. Nuvia HR-S media delivers the resolution performance that bioprocess scientists need to address this challenge. An example of a high-resolution separation is shown in Figure 1, where a mixture of monomer and aggregate was separated on Nuvia HR-S media. From a starting aggregate concentration of 8.9%, the final eluate pool contained 0.11% residual aggregate with an overall monomer recovery of 82%. Furthermore, as shown in Figure 2, better resolution was obtained using the Nuvia HR-S media with near baseline resolution of a protein mixture compared to Media 1, another commercially available high-resolution small particle cation exchanger.



**Fig. 1. Monoclonal antibody separation on Nuvia HR-S media.** A, chromatogram of the purification of monomer from aggregate; B, chromatography conditions. A<sub>280</sub> (—); pH (—); gradient elution (—).



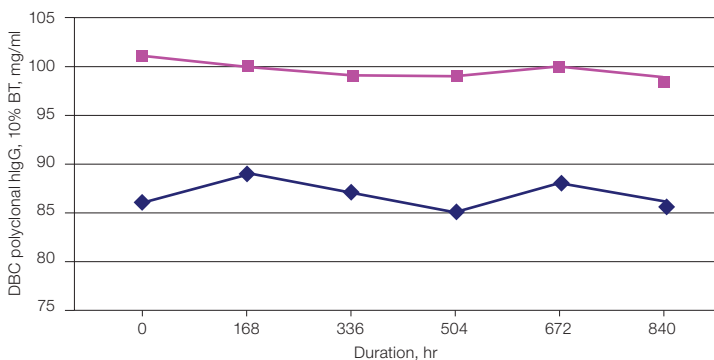


**Fig. 2. Resolution performance of Nuvia HR-S media.** Comparison of Nuvia HR-S media to another commercially available small particle cation exchanger (Media 1). Column size, 7 x 56 mm. A protein standard mixture of myoglobin, ribonuclease, and cytochrome C was loaded onto the columns in 20 mM sodium phosphate, pH 7.0, washed, and then eluted with a gradient of 20 mM sodium phosphate, pH 7.0 + 1 M NaCl. Nuvia HR-S (—); Media 1 (—).

### Consistent and Reproducible Performance

Chromatography media used in downstream purification are required to perform consistently, even after repeated exposure to caustic sanitization protocols. Nuvia HR-S media binding capacity and protein recovery remained unchanged after exposure to 840 hr of 1.0 N NaOH (equivalent to 420 cycles at 2-hr sanitization hold), thus ensuring the media can be used repeatedly without compromising performance, as shown in Figure 3.

Produced in a validated manufacturing process under strict specifications, the cornerstone of Nuvia HR-S media is batch-to-batch reproducibility. With more than 50 years of experience in chromatography, Bio-Rad understands and is committed to maintaining the highest level of quality and security of supply.



**Fig. 3. Stability of Nuvia HR-S media.** Results of hlgG binding capacity after exposing Nuvia HR-S media to 1.0 N NaOH. 10% breakthrough (—); % recovery (—). BT, breakthrough; DBC, dynamic binding capacity.

### Technical Assistance

Bio-Rad is an ISO 9001 registered corporation. A regulatory support file for FDA/EMA filing is available for Nuvia HR-S media upon request. For additional information and technical assistance, contact your local Bio-Rad office.

### Properties of Nuvia HR-S Media

Property	Description
Type of ion exchanger	Strong cation
Functional group	—SO <sup>3-</sup>
Total ionic capacity	100–180 µeq/ml
Dynamic binding capacity*	≥70 mg/ml at 300 cm/hr
Shipping counter ion	Na <sup>+</sup>
Median particle size	50 ± 10 µm
Recommended linear flow rate	50–200 cm/hr
Chemical stability	
1.0 N NaOH (20°C)	Up to 5 weeks (840 hr)
0.1 N NaOH (20°C)**	Up to 5 years
Compression factor	1.25 (settled bed volume/packed bed volume)
pH stability	
Short-term	2–14
Long-term**	4–13
Shipping solution	20% ethanol
Regeneration	1–2 M NaCl
Sanitization	0.5–1.0 N NaOH
Storage conditions	20% ethanol or 0.1 N NaOH

\* 10% breakthrough capacity determined with 5.0 mg/ml human IgG in 20 mM Na acetate, pH 5.0.

\*\* Data derived under accelerated conditions at 60°C.

Larger volumes and special packaging for industrial applications are available on request.

For more information about Bio-Rad's complete line of process chromatography media, visit us on the Web at [www.bio-rad.com/process](http://www.bio-rad.com/process).



### Ordering Information

Catalog #	Description
156-0511	Nuvia HR-S Media, 25 ml
156-0513	Nuvia HR-S Media, 100 ml
156-0515	Nuvia HR-S Media, 500 ml
156-0517	Nuvia HR-S Media, 10 L
732-4707	Foresight™ Nuvia™ HR-S Plate, 20 µl
732-4831	Foresight Nuvia HR-S RoboColumn Unit, 200 µl
732-4832	Foresight Nuvia HR-S RoboColumn Unit, 600 µl
732-4723	Foresight Nuvia HR-S Column, 1 ml
732-4743	Foresight Nuvia HR-S Column, 5 ml



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