

POROS® XS Cation Exchange Resin

High capacity + high resolution + high salt tolerance

- Dynamic binding capacity for proteins, greater than 100 mg/mL at 5% breakthrough
- High resolution using optimized 50 µm particle size for improved impurity clearance
- Robust salt tolerance that maintains dynamic binding capacity up to 150 mM NaCl (15 mS/cm)

Introduction

Today's higher-titer biotherapeutic processes create a host of downstream purification challenges and bottlenecks. Traditionally, high-capacity resins fail to achieve high resolution in the purification of monoclonal antibodies and recombinant proteins. In addition, maintaining protein binding capacity in the presence of higher salt concentrations is a hurdle in streamlining process flow.

The need for a resin that delivers high capacity and high resolution in a wide range of salt concentrations is now critical, especially in downstream polishing steps.

A resin that delivers the combination of high capacity, high resolution, and high salt tolerance can lead to increased process efficiency and help enable a faster time to market for the product.

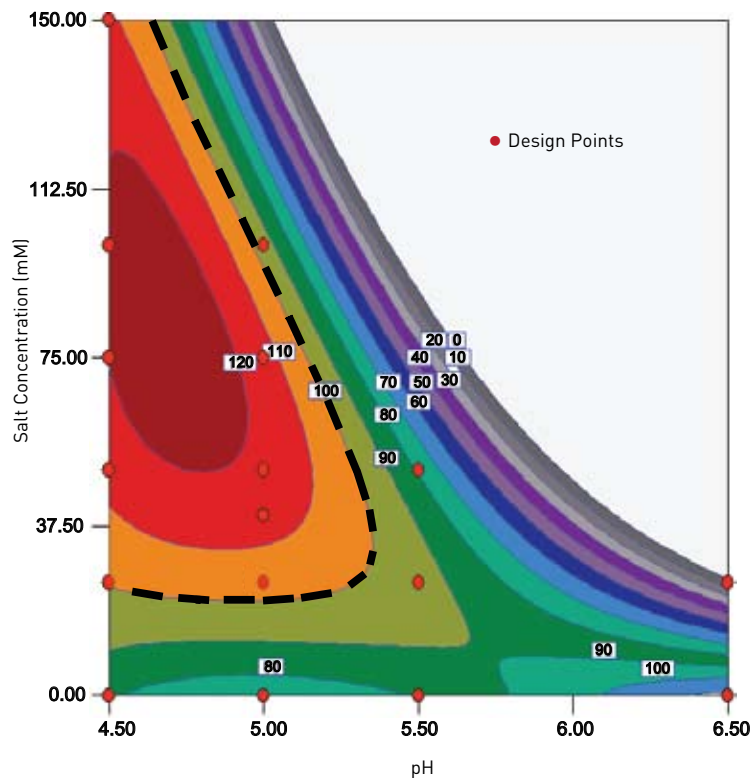


Figure 1. 5% Breakthrough IgG binding capacity vs. salt concentration and pH.

High capacity is obtained under a wide range of process conditions. The area inside the dotted line indicates the condition at which greater than 100 mg/mL binding capacity of IgG could be obtained. Column: 0.46 cmD x 20 cmL; Buffer: 20 mM MES; Load conditions: 5 mg/mL IgG; Flow rate: 300 cm/h

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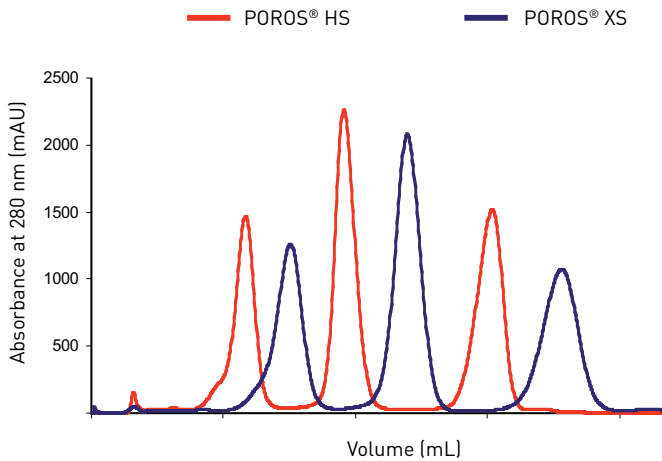


Figure 2. Separation capability on POROS® HS and POROS® XS resin. Column: 1 cmD x 20 cmL; Gradient: 10-50% B, 7.5 CV; Buffer A: 20 mM MES, 25 mM NaCl pH 6.2; Buffer B: 20 mM MES, 1M NaCl pH 6.2; Flow rate: 300 cm/h
Sample: Chymotrypsinogen, Cytochrome C, Lysozyme

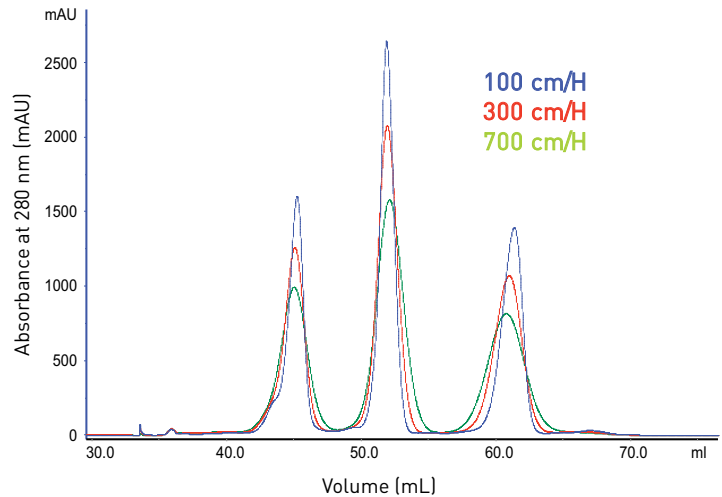


Figure 3. Resolution over a range of operating flow rates. Column: 0.46 cmD x 20 cmL; Gradient: 10-100% B, 16 CV; Buffer A: 20 mM MES, 25 mM NaCl pH 6.2; Buffer B: 20 mM Tris, 1.0 M NaCl, pH 6.2; Flow rate: 300 cm/h
Sample: Chymotrypsinogen, Cytochrome C, Lysozyme

POROS® XS Cation Exchange Resin

POROS® XS resin, from Life Technologies, is the first high-capacity, high-resolution resin that allows loading in the presence of up to 15 mS/cm NaCl to more than 100 mg/mL capacity, while delivering unprecedented separation capability.

A major improvement on traditional cation exchangers, POROS® XS resin sets the standard for cation exchange chromatography.

- Dynamic binding capacity leads to reduced column size, smaller footprint, decreased buffer usage, and reduced cycling.
- High resolution supports better product yield and improved impurity clearance.
- Robust salt tolerance allows improved process flexibility, and alignment and process flow streamlining.
- Low back pressure and linear pressure response help improve scalability.
- Rigid polymeric bead with covalent surface chemistry makes for easier handling and packing, and superior physical and chemical stability, resulting in a robust manufacturing process.

Dynamic binding capacity

POROS® XS resin delivers high capacity, greater than 100 mg/mL at 5% breakthrough, over a broad range of process conditions. Figure 1 demonstrates unparalleled high binding capacity across a broad range of pH and salt conditions. Higher dynamic binding capacity was achieved through the optimization of the base bead pore structure and the surface chemistry.

High resolution

With an optimized 50 µm particle size, POROS® XS resin maintains the superior resolution capability of POROS® HS resin (Figure 2) while addressing the challenging impurity levels associated with high titer processes. Resolution is consistent across a wide range of operating flow rates (Figure 3) and maintained independent of protein load (Figure 4).

Robust salt tolerance

POROS® XS resin delivers high and consistent protein capacity across a broad range of salt concentrations (Figure 5) up to 150 mM NaCl (15 mS/cm conductivity). The flexibility of loading columns, under higher conductivity conditions, helps enable the reduction or elimination of the dilution of column feed streams or the removal of unit operations, such as tangential flow filtration. The optimized surface ionic capacity of POROS® XS resin minimizes competitive binding between the protein of interest and the counterion, resulting in superior salt tolerance.

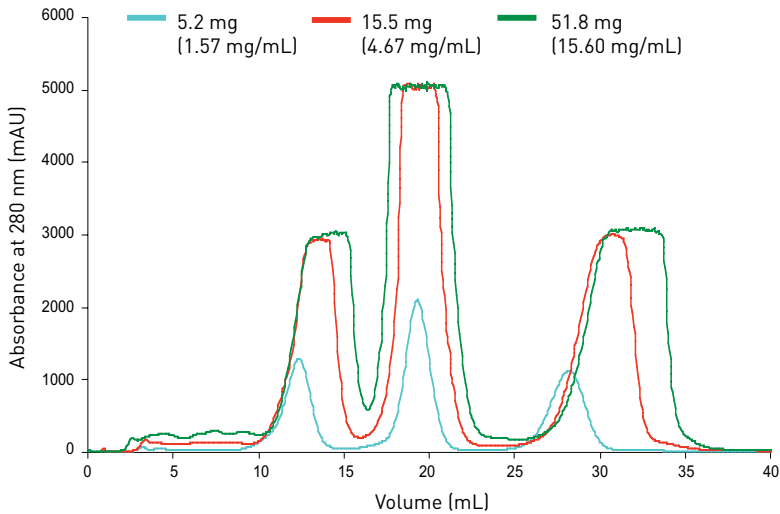


Figure 4. Resolution as a function of protein loading.
 Column: 0.46 cmD x 20 cmL; Gradient: 10–100% B, 16 CV; Buffer A: 20 mM MES, 25 mM NaCl pH 6.2; Buffer B: 20 mM Tris, 1.0 M NaCl, pH 6.2
 Sample: Chymotrypsinogen, Cytochrome C, Lysozyme

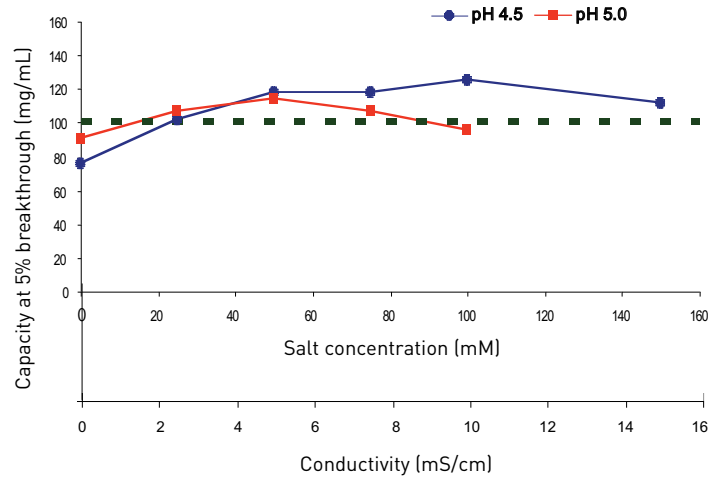
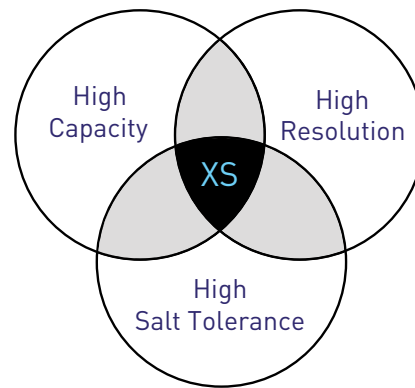


Figure 5. IgG binding capacity vs. salt concentration.
 Column: 0.46 cm x 20 cmL; Buffer: 20 mM MES
 Load conditions: 5 mg/mL IgG; Flow rate: 300 cm/h

State-of-the-art manufacturing capability

Life Technologies manufactures POROS® XS resin from approved raw materials to finished product using advanced, proprietary processes that make us unique in this industry. A 30,000 square foot, state-of-the-art chemical facility, in Bedford, Massachusetts, is dedicated to the production of all the POROS® chromatography resins. Quality testing is performed at all stages of the POROS® XS process to ensure excellent lot-to-lot consistency. POROS® XS is backed up with both a drug master file and regulatory support package.

POROS® chromatography resins are manufactured under ISO 9001:2008 and ISO 13485:2003 standards. The facility and quality systems are routinely audited by regulated biopharmaceutical companies.



Conclusion

POROS® XS resin sets the bar in fulfilling the most important demands of today's high-titer downstream purification processes. This breakthrough cation exchange chromatography resin provides a unique combination of high capacity, high resolution, and high salt tolerance.

The market-leading performance from this dynamic feature set surpasses that of other commercially available cation exchange resins. POROS® XS resin helps enable improved product yield, greater process flexibility, and streamlined downstream processing.

Ordering information

Description	Pack Size	Part Number
POROS® XS Cation Exchange Resin	25 mL	4404339
POROS® XS Cation Exchange Resin	50 mL	4404338
POROS® XS Cation Exchange Resin	250 mL	4404337
POROS® XS Cation Exchange Resin	1,000 mL	4404336
POROS® XS Cation Exchange Resin	5,000 mL	4404335
POROS® XS Cation Exchange Resin	10,000 mL	4404334

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Printed in the USA. C021707 1210

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