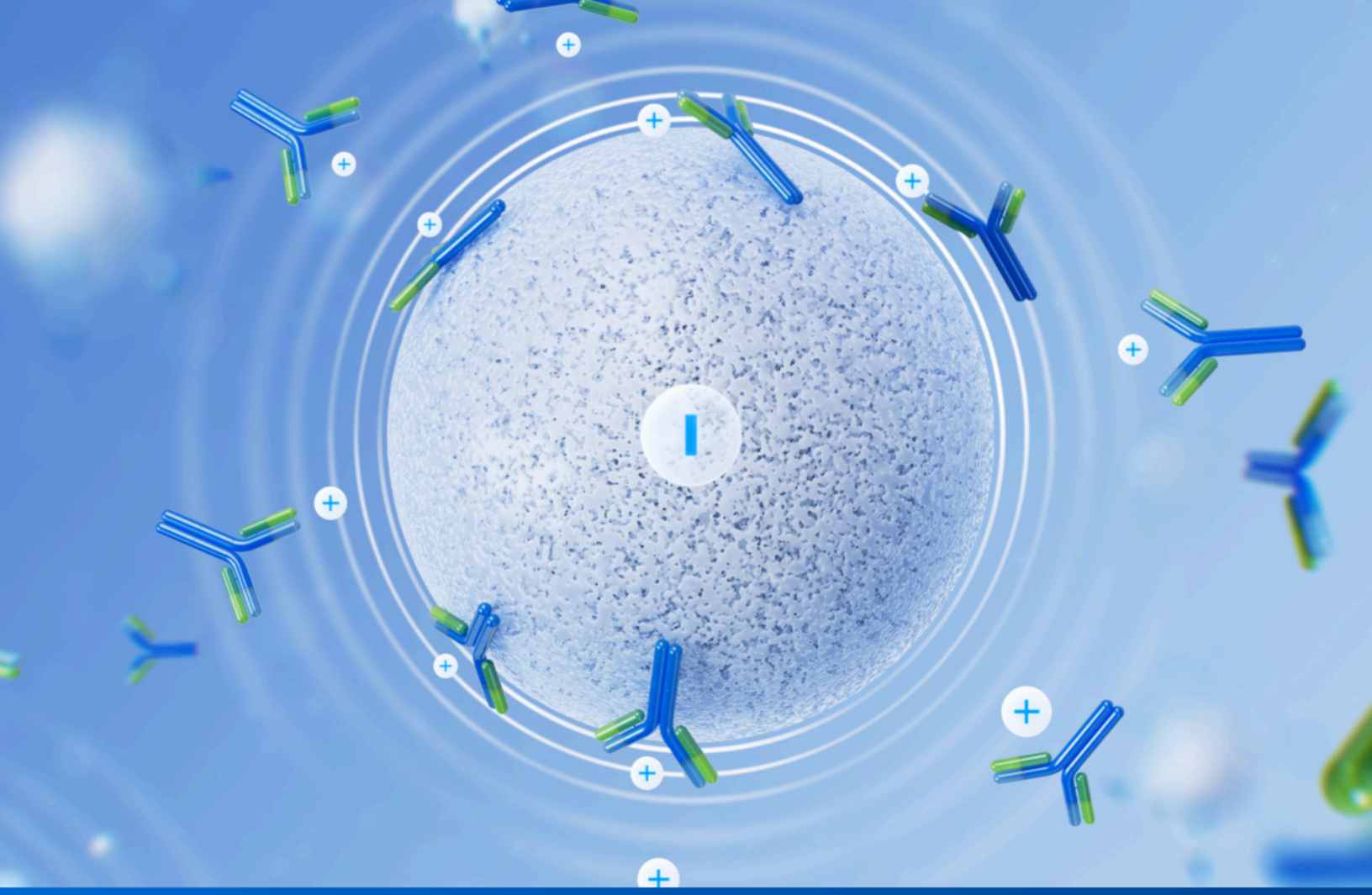


Ion Exchange Resin Selection Guide

ECOLAB®



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Introduction

The use of monoclonal antibodies (mAbs) in the development of therapeutic medicines is revolutionizing patient care and has become an essential tool in fighting a variety of conditions, including cancer, autoimmune disorders, and cardiovascular diseases, among others.

Purification of these molecules is a critical step within the broader manufacturing process to ensure impurities from biosynthesis are removed and do not impact the quality of the final biological product.

A typical purification workflow involves three stages – capture, intermediate purification, and polishing. The capture and intermediate stages utilize affinity chromatography resins, followed by one or two ‘polishing’ steps to remove trace impurities.

When designing a purification workflow, emphasis is most frequently placed on the capture stage and the selection of an affinity resin. The use of a suitable affinity resin during this stage can achieve > 95% purity of the end product and accounts for the majority of the costs associated with purification.

However, selecting appropriate chromatography resins for the polishing stage is critical to achieving process robustness and ensuring overall performance.

This Selection Guide discusses the use of Purolite™ Ion Exchange Resins from Ecolab to perform the final polishing stage of mAb purification, highlighting the benefits of Jetting technology to manufacture chromatography resins.

Jetting Manufacturing of Chromatography Resins

Both the resin material and manufacturing process will significantly impact the resin properties and, in turn, the resin performance.

Chromatography resins can be made of various materials. Purolite Resins are made using agarose, an ideal material for bioprocessing due to its hydrophilic nature and strong physical and chemical properties. These properties enable agarose-based resins to support purification at scale.

The manufacturing method employed for resin production is also important. The traditional method of agarose bead production, batch emulsification, involves dissolving the agarose in a chemical solvent, stirring the mixture to reduce the particle size, and extensively sieving the beads to help reduce the distribution in the range of bead sizes.

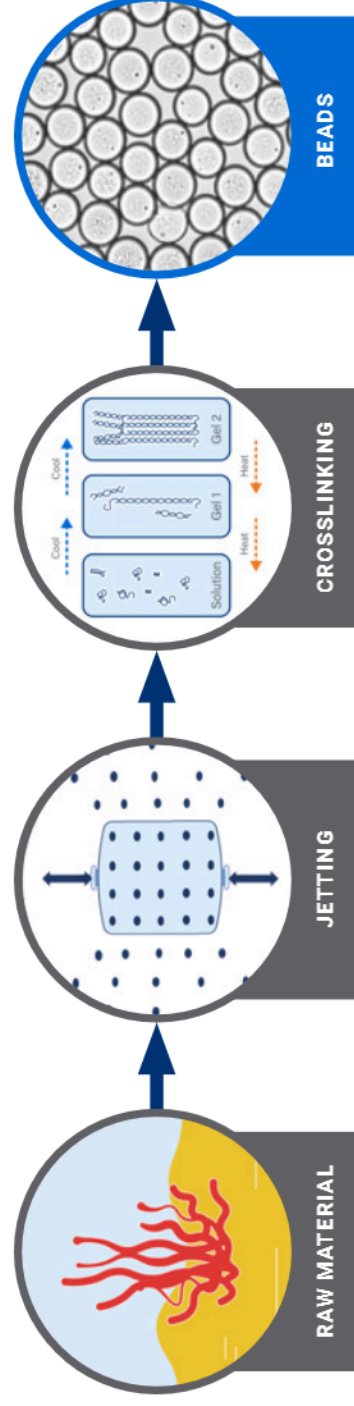
Ecolab employs the patented method of Jetting manufacturing to produce resin beads. The Jetting manufacturing process uses no chemical solvents and reduces the sieving process, allowing for shorter lead times while maintaining a narrower bead size distribution than traditional methods.

During the Jetting manufacturing process, agarose is dissolved in water and pushed through precisely sized pores in a canister into a bath of mineral oil. The canister oscillates vertically at a consistent rate, “breaking” the agarose solution into uniformly sized droplets. The droplets harden as the beads cool and undergo cross-linking. The resulting beads are uniform in size, limiting the amount of sieving required and allowing the entire batch to be utilized for chromatography.

FIGURE 1

Schematic of the Jetting Process

Unlike traditional emulsification techniques, limited sieving is required in the Jetting process, resulting in greater yield.



In this example, emulsified beads are targeted at 85 microns (μm) and the Jetted beads are targeted at 50 μm . A marked difference in particle size distribution can be seen when comparing Jetted resin beads with emulsified resin beads.

Jetting manufacturing produces beads that are more uniform in size, centering on a single mean particle size. In contrast, emulsified beads exhibit a broad distribution of particle sizes within a specified range following the sieving process.

The consistent bead size of Jetted resins enhances mass transfer and aids in target binding. In addition, reducing the sieving process produces a greater yield per run, helping reduce lead time.



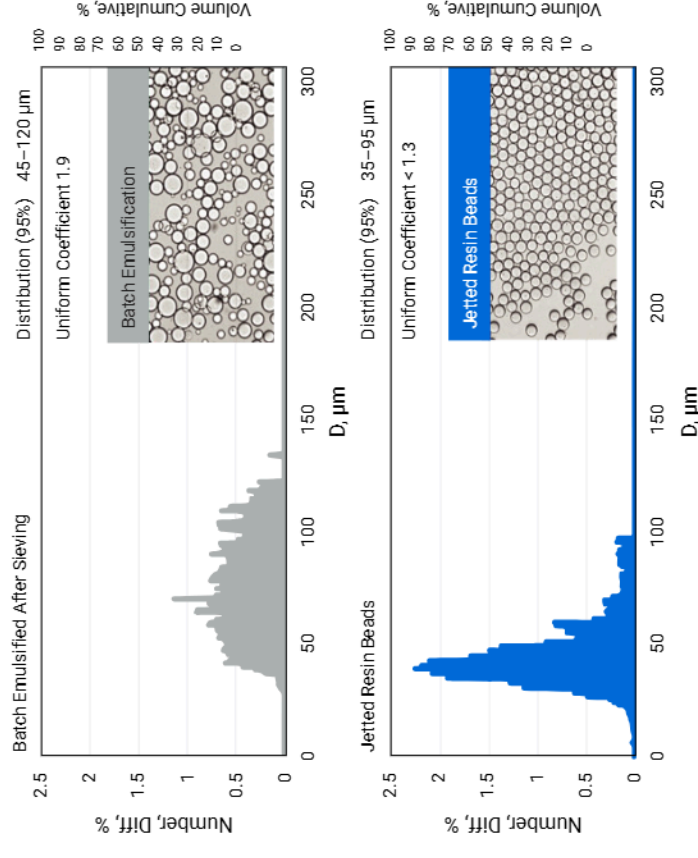
Learn how Jetting technology supports sustainability and improves manufacturing efficiency.

www.puroliteresins.com/index/bioprocessing/jetting-technology

FIGURE 2

Particle Size Distribution Comparison

Graph and microscope comparison of emulsified resin beads after extensive sieving and Jetted resin beads with limited sieving. In this comparison, the emulsified bead is targeted at 85 μm , with an average range of 45–120 μm . The Jetted bead is targeted at 50 μm .



Ion Exchange Chromatography Resins

Jetting technology is employed to manufacture Purolite Resins (Praesto SP and Praesto Q) for ion exchange chromatography, in a range of particle sizes from 35 µm to 90 µm.

For cation exchange, jetted beads are modified with a Sulphonyl Propyl (SP) ligand for cation exchange. For anion exchange, jetted beads are modified with a Quaternary Amine (Q) ligand.

A benefit of the Jetting process is the control it enables over particle size – requiring only a simple change in the size of the apertures employed. This allows for changes in the mean particle size without impacting surface chemistry or ligand density.

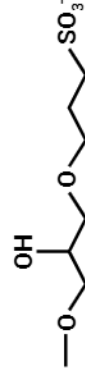
Both Praesto SP and Praesto Q portfolios leverage this benefit to offer resins in 35 µm, 45 µm, 65 µm, and 90 µm particle sizes, the largest range of particle sizes commercially available for ion exchange resins.

When selecting an ion exchange resin, performance should be viewed as a balance among resolution, capacity, recovery, and flow rate (speed).

FIGURE 3

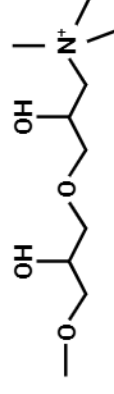
Overview of Ion Exchange Particle Size and Chemical Makeup

Praesto SP and Praesto Q resins are available in four particle sizes to optimize performance. The mean particle sizes are noted below the ligand designation.



Praesto SP Resins

Sulphopropyl cation exchange
(35 µm, 45 µm, 65 µm, and 90 µm)



Praesto Q Resins

Quaternary amine anion exchange
(35 µm, 45 µm, 65 µm, and 90 µm)

Typically, larger beads improve pressure-flow properties by reducing back-pressure in packed columns, allowing for greater throughput of sample feed. In comparison, smaller beads improve resolution and allow greater binding capacity at any given residence time due to the faster mass transfer offered by a smaller bead.

FIGURE 4

Illustration of Balancing Performance across Particle Sizes

Illustration of the effects of increasing particle size on speed (pressure-flow), resolution, and capacity.

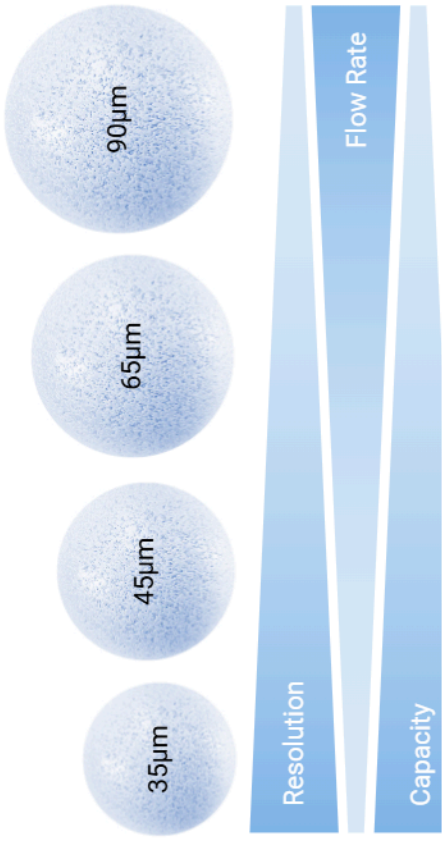
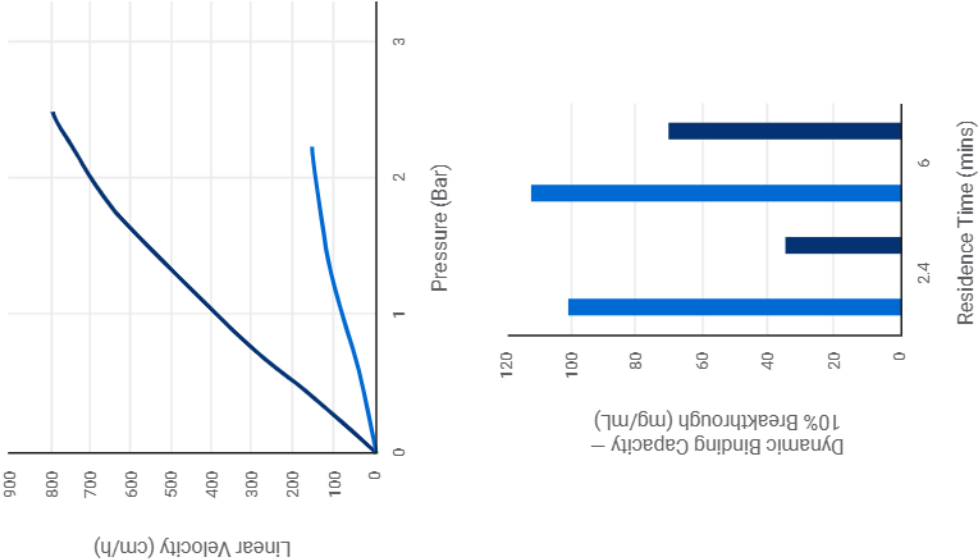


FIGURE 5

Key Performance Parameters of Praesto SP35 and Praesto SP90

Comparison of Praesto SP35 (blue) and Praesto SP90 (dark blue) demonstrating the balance between flow properties and dynamic binding capacity.



Varying binding capacity across particle sizes can be visualized by examining the degree of bead saturation as a function of residence time using red-labeled bovine serum albumin for three particle sizes of ion exchange resin.

Different particle sizes hold differential saturation kinetics — the diffusion rate in each case is largely similar, but the rate of bead saturation varies depending on bead size. The larger the bead, the more time required for saturation. In addition, smaller beads provide higher binding capacity at shorter residence times due to mass transfer.

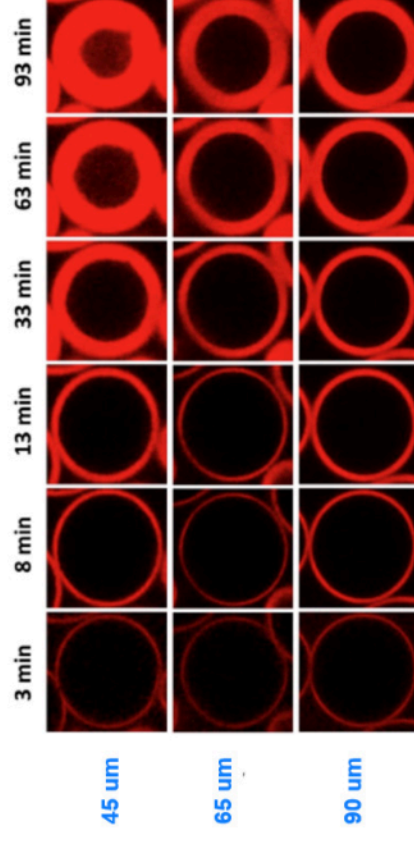
Bead size is a critical component to consider when selecting a resin for ion exchange chromatography, as it modifies purification performance.

FIGURE 6

Illustration of Bead Saturation as a Function of Residence Time

Illustration of red-labeled bovine serum albumin to compare saturation in relation to residence time across three particle sizes of Purolite ion exchange resins.

Data from 'Characterization of ion exchange chromatography resins for therapeutic protein manufacture' DEng Thesis, Greta Jasulaityte, UCL. Open access link: <https://discovery.ucl.ac.uk/id/eprint/10139127/>



Ion Exchange Resins in Monoclonal Antibody Polishing

The use of ion exchange resins in the polishing stage typically follows the use of affinity resins used in the capture stage. The most common approach to polishing includes a process of cation exchange operating in bind and elute mode and anion exchange operating in flowthrough mode.

FIGURE 7

Three-Stage Purification Workflow

A typical purification workflow includes a two-step polishing regime, with cation exchange operating in bind and elute mode and anion exchange operating in flow-through mode.



Bind and Elute Polishing

Cation exchange resins, including Praesto SP, are most frequently used in bind and elute mode during the polishing stage of mAb purification. In this chromatographic regime, conditions are established to bind the positively charged mAb to the resin, while negatively charged impurities are washed from the column. Conditions are then altered to elute the bound antibody.

The isoelectric point (pI) is a critical parameter used in bind and elute mode. It is the pH at which a protein or other biomolecule carries no net electrical charge, and isoelectric focusing separates molecules based on their pI values.

As a result, the pI of the target protein or biomolecule can be used to control the binding and elution process.

By controlling the pH of the buffer during binding and elution steps according to the pI of the target protein, cation exchange resins can effectively separate and purify proteins and biomolecules based on their isoelectric points.

BINDING

At a pH below the target protein's pI, the protein carries a net positive charge. Cation exchange resins have negatively charged functional groups that can interact with the positively charged proteins, causing them to bind to the resin.

WASHING

Once the target protein is bound to the resin, the column can be washed with a buffer at a slightly lower pH to remove any non-specifically bound proteins or impurities.

ELUTION

To elute the target protein from the resin, the pH of the elution buffer is raised above the protein's pI. At this higher pH, the protein becomes negatively charged, weakening its interaction with the cation exchange resin and allowing it to be eluted from the column.

Flow Through Polishing with Praesto Q Resins

An alternative to bind and elute mode for polishing monoclonal antibodies, often used with anion exchange resins, is flow-through mode. In this chromatographic regime, conditions are set so the target mAb is positively charged, while impurities are negatively charged. During this step, the mAb is eluted while the contaminants are bound and then removed from the resin via an elution step.

In flow-through mode, the isoelectric point (pI) is not utilized the same as with bind and elute. Instead, the pI helps determine how the target protein or biomolecule behaves, affecting the separation and purification process.

The pI is indirectly utilized in flow-through in anion exchange resins in the following ways:

1. **UNDERSTANDING THE PL**

The pI of a protein is the pH at which the protein carries no net electrical charge. Below the pI, the protein carries a net positive charge. Above the pI, it carries a net negative charge.

2. **INTERACTIONS WITH ANION EXCHANGE RESIN**

Anion exchange resins have positively charged groups that interact with negatively charged molecules. When a mixture of proteins or biomolecules is passed through the resin, negatively charged molecules will bind to it, while positively charged or neutral molecules will flow through.

3. **SEPARATION BASED ON CHARGE**

The pI of the molecules in the feed affects their interaction with the anion exchange resin. Molecules with a pI below the operational pH will strongly bind to the resin, while those with a pI above it will flow through. Molecules with a pI close to the operational pH may behave inconsistently.

Though not a primary parameter in flow-through mode, pI influences the charge state of the molecules, governing their interaction with the resin. Understanding the pI of the molecules in the feed helps to optimize the separation and purification process.

FIGURE 8

Bind and Elute Mode

Schematic of bind and elute mode during the polishing stage, where the molecule of interest is bound to the resin. In this schematic, orange, red, and green shapes represent impurities, and light blue arrows represent elution.

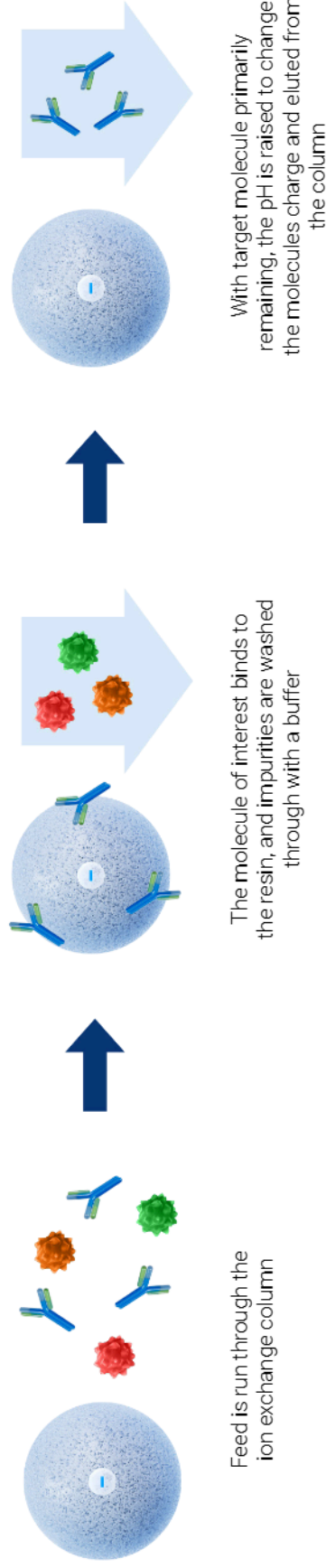
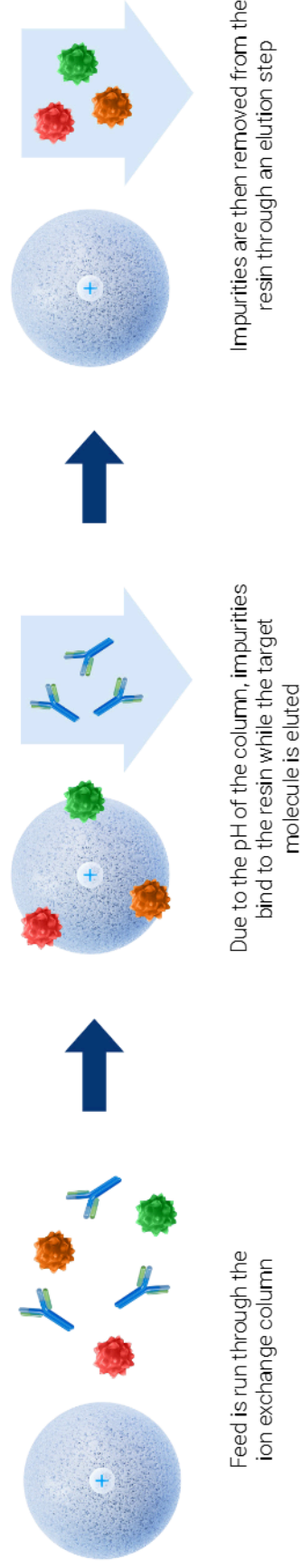


FIGURE 9

Flow-through Mode

Schematic of flow-through mode during the polishing stage, where impurities are bound to the resin. In this schematic, orange, red, and green shapes represent impurities, and light blue arrows represent elution.



Impurity Removal

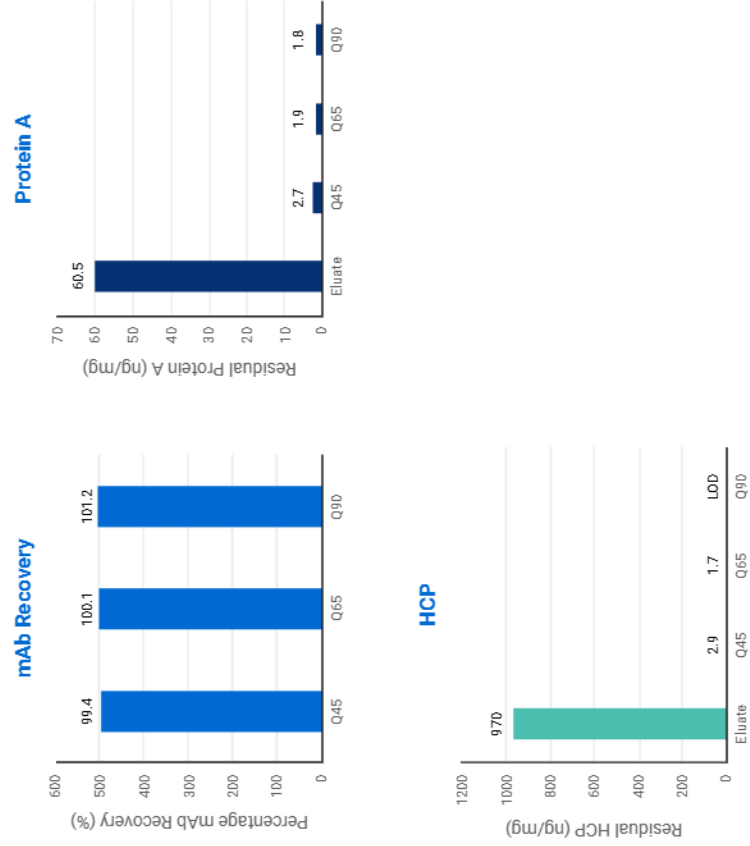
The purpose of polishing chromatography is to eliminate any remaining impurities that persist after the capture and intermediate purification stages have been completed. This includes removing host cell proteins (HCPs) and cleaved protein A from the affinity resin.

Though this stage aims to remove impurities, high recovery of monoclonal antibodies remains a priority. Purolite ion exchange resins offer sufficient recovery of mAbs while removing high levels of HCPs and leached protein A.

FIGURE 10

mAb Recovery, HCP clearance, and Leached Protein A Removal

Across three sizes of Praesto Jetted Q to indicate the performance of Purolite Resins in ion exchange chromatography.



Conclusion

Employing ion exchange resins in bind and elute or flow-through polishing steps is essential for lowering impurity levels in monoclonal antibodies intended for therapeutic applications.

Jetting technology, used to create Purolite ion exchange resins, produces uniform beads across various particle sizes (35 µm, 45 µm, 65 µm, 90 µm). Resin selection can be easily determined based on flow properties, resolution, and capacity to fit any purification workflow.

Praesto Jetted SP and Praesto Jetted Q resins provide excellent performance for the polishing stage of protein purification, efficiently removing impurities without compromising yield.

Ordering Information

Purolite™ Praesto™ Jetted Q35

Product Description	Legacy Material Number	EBS SAP Material Number
Praesto Jetted Q35 – 25ml	PR00436-166	6601317
Praesto Jetted Q35 – 100ml	PR00436-164	6601315
Praesto Jetted Q35 – 500ml	PR00436-165	6601316
Praesto Jetted Q35 – 1L	PR00436-310	6601318
Praesto Jetted Q35 – 5L	PR00436-311	6601319
Praesto Jetted Q35 – 10L	PR00436-312	6601320
Praesto Jetted Q35 (1ml) MiniChrom Columns	PR00436-175	6601161
Praesto Jetted Q35 (5ml) MiniChrom Columns	PR00436-176	6601162
Praesto Jetted Q35 (200uL) RoboColumn Column	PR00436-174	6601160
Praesto Jetted Q35 (600uL) RoboColumn Column	PR00436-279	6601165
Praesto Jetted Q35 (1ml) HT	PR00436-275	6601163
Praesto Jetted Q35 (5ml) HT	PR00436-276	6601164

Purolite™ Praesto™ Jetted Q45

Product Description	Legacy Material Number	EBS SAP Material Number
Praesto Q45 – 25ml	PR00246-166	6601239
Praesto Q45 – 100ml	PR00246-164	6601237
Praesto Q45 – 500ml	PR00246-165	6601238
Praesto Q45 – 1L	PR00246-310	6601240
Praesto Q45 – 5L	PR00246-311	6601241
Praesto Q45 – 10L	PR00246-312	6601242
Praesto Q45 (1ml) MiniChrom Columns	PR00246-175	6601101
Praesto Q45 (5ml) MiniChrom Columns	PR00246-176	6601102
Praesto Q45 (200uL) RoboColumn Column	PR00246-174	6601100
Praesto Q45 (600uL) RoboColumn Column	PR00246-279	6601105
Praesto Q45 (1ml) HT Column	PR00246-275	6601103
Praesto Q45 (5ml) HT Column	PR00246-276	6601104

Purolite™ Praesto™ Jetted Q65

Product Description	Legacy Material Number	EBS SAP Material Number
Praesto Q65 – 25ml	PR00266-166	6601257
Praesto Q65 – 100ml	PR00266-164	6601255
Praesto Q65 – 500ml	PR00266-165	6601256
Praesto Q65 – 1L	PR00266-310	6601258
Praesto Q65 – 5L	PR00266-311	6601259
Praesto Q65 – 10L	PR00266-312	6601260
Praesto Q65 (1ml) MiniChrom	PR00266-175	6601113
Praesto Q65 (5ml) MiniChrom	PR00266-176	6601114
Praesto Q65 (200µl) Robocolumn	PR00266-174	6601112
Praesto Q65 (600µl) Robocolumn	PR00266-279	6601117
Praesto Q65 (1ml) HT Column	PR00266-275	6601115
Praesto Q65 (5ml) HT Column	PR00266-276	6601116

Purolite™ Praesto™ Jetted Q90

Product Description	Legacy Material Number	EBS SAP Material Number
Praesto Q90 – 25ml	PR00296-166	6601275
Praesto Q90 – 100ml	PR00296-164	6601273
Praesto Q90 – 500ml	PR00296-165	6601274
Praesto Q90 – 1L	PR00296-310	6601276
Praesto Q90 – 5L	PR00296-311	6601277
Praesto Q90 – 10L	PR00296-312	6601278
Praesto Q90 (1ml) MiniChrom Columns	PR00296-175	6601125
Praesto Q90 (5ml) MiniChrom Columns	PR00296-176	6601126
Praesto Q90 (200uL) RoboColumn Column	PR00296-174	6601124
Praesto Q90 (600uL) RoboColumn Column	PR00296-279	6601129
Praesto Q90 (1ml) HT Column	PR00296-275	6601127
Praesto Q90 (5ml) HT Column	PR00296-276	6601128

Purolite™ Praesto™ Jetted SP35

Product Description	Legacy Material Number	EBS SAP Material Number
Praesto Jetted SP35 – 25ml	PR00432-166	6601311
Praesto Jetted SP35 – 100ml	PR00432-164	6601309
Praesto Jetted SP35 – 500ml	PR00432-165	6601310
Praesto Jetted SP35 – 1L	PR00432-310	6601312
Praesto Jetted SP35 – 5L	PR00432-311	6601313
Praesto Jetted SP35 – 10L	PR00432-312	6601314
Praesto Jetted SP35 (1ml) MiniChrom Columns	PR00432-175	6601155
Praesto Jetted SP35 (5ml) MiniChrom Columns	PR00432-176	6601156
Praesto Jetted SP35 (200ul) RoboColumn Column	PR00432-174	6601154
Praesto Jetted SP35 (600ul) RoboColumn Column	PR00432-279	6601159
Praesto Jetted SP35 (1ml) HT	PR00432-275	6601157
Praesto Jetted SP35 (5ml) HT	PR00432-276	6601158

Purolite™ Praesto™ Jetted SP45

Product Description	Legacy Material Number	EBS SAP Material Number
Praesto SP45 – 25ml	PR00242-166	6601233
Praesto SP45 – 100ml	PR00242-164	6601231
Praesto SP45 – 500ml	PR00242-165	6601232
Praesto SP45 – 1L	PR00242-310	6601234
Praesto SP45 – 5L	PR00242-311	6601235
Praesto SP45 – 10L	PR00242-312	6601236
Praesto SP45 (1ml) MiniChrom Columns	PR00242-175	6601095
Praesto SP45 (5ml) MiniChrom Columns	PR00242-176	6601096
Praesto SP45 (200uL) RoboColumn Column	PR00242-174	6601094
Praesto SP45 (600uL) RoboColumn Column	PR00242-279	6601099
Praesto SP45 (1ml) HT Column	PR00242-275	6601097
Praesto SP45 (5ml) HT Column	PR00242-276	6601098

Purolite™ Praesto™ Jetted SP65

Product Description	Legacy Material Number	EBS SAP Material Number
Praesto SP65 – 25ml	PR00262-166	6601251
Praesto SP65 – 100ml	PR00262-164	6601249
Praesto SP65 – 500ml	PR00262-165	6601250
Praesto SP65 – 1L	PR00262-310	6601252
Praesto SP65 – 5L	PR00262-311	6601253
Praesto SP65 – 10L	PR00262-312	6601254
Praesto SP65 (1ml) MiniChrom Columns	PR00262-175	6601107
Praesto SP65 (5ml) MiniChrom Columns	PR00262-176	6601108
Praesto SP65 (200uL) RoboColumn Column	PR00262-174	6601106
Praesto SP65 (600uL) RoboColumn Column	PR00262-279	6601111
Praesto SP65 (1ml) HT Column	PR00262-275	6601109
Praesto SP65 (5ml) HT Column	PR00262-276	6601110

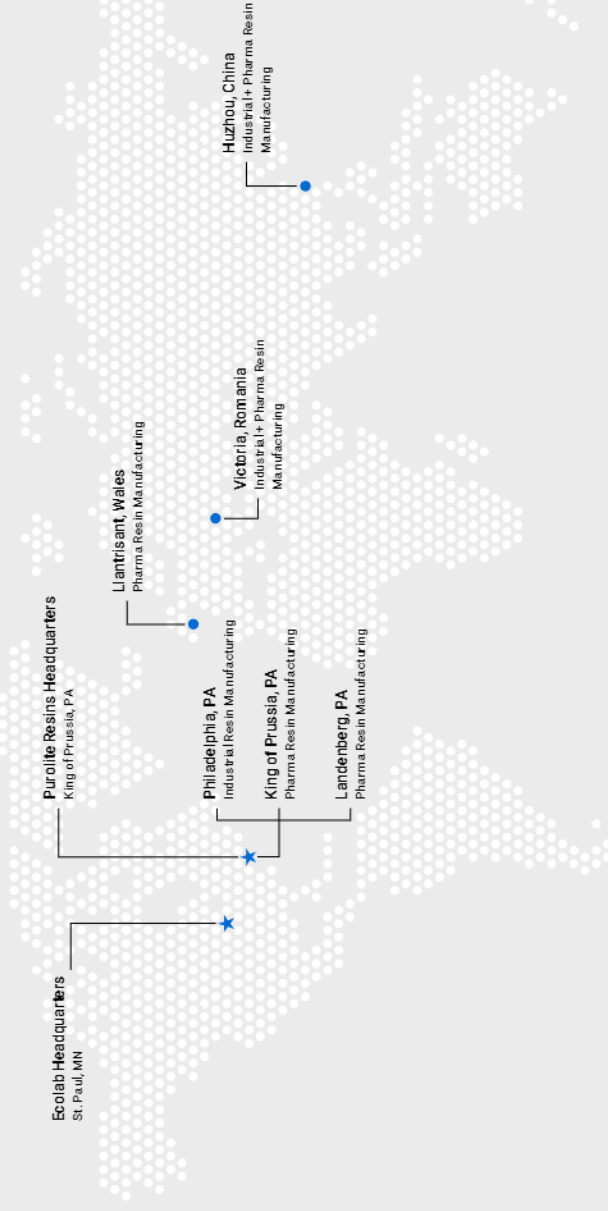
Purolite™ Praesto™ Jetted SP90

Product Description	Legacy Material Number	EBS SAP Material Number
Praesto SP90 – 25ml	PR00292-166	6601269
Praesto SP90 – 100ml	PR00292-164	6601267
Praesto SP90 – 500ml	PR00292-165	6601268
Praesto SP90 – 1L	PR00292-310	6601270
Praesto SP90 – 5L	PR00292-311	6601271
Praesto SP90 – 10L	PR00292-312	6601272
Praesto SP90 (1ml) MiniChrom Columns	PR00292-175	6601119
Praesto SP90 (5ml) MiniChrom Columns	PR00292-176	6601120
Praesto SP90 (200uL) RoboColumn Column	PR00292-174	6601118
Praesto SP90 (600uL) RoboColumn Column	PR00292-279	6601123
Praesto SP90 (1ml) HT Column	PR00292-275	6601121
Praesto SP90 (5ml) HT Column	PR00292-276	6601122

Ecolab is a global developer, manufacturer, and supplier of Purolite™ Resins including ion exchange, catalyst adsorbent and advanced polymers that make the world cleaner and healthier.



PuroliteResins.com



We're ready to solve your process challenges.

For further information on products and services, visit PuroliteResins.com or complete a Contact Us form via PuroliteResins.com/contact-us or use the QR code.

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