

Ion Exchange Resins

Modern, Advanced High-Flow, Highly Cross-Linked Agarose Resins For Improved Process Economics





Why Purolite[®]?

For over 35 years, Purolite has supplied specialty ion exchange resin technology to industries within complex regulatory environments, including biotechnology, pharmaceutical, food, fine chemical and electric power generation. Purolite is the only global company to focus 100% on resin technology.

Security of Supply

Ensuring reliable availability of products in case of emergency is vital to customers and of paramount importance to Purolite.

As a leading supplier of resin media to the world's most regulated industries, Purolite has a real-world security-of-supply system in place to support your process requirements for business continuity in the instance of natural disaster or emergency.

Purolite has manufacturing facilities at 3 strategic global locations in the USA, Asia and Europe, and is currently building its 4th manufacturing plant in the UK. This facility will be the second largest agarose manufacturing plant globally, with a capacity of 100,000 L per annum.

Currently, approximately 90% of all biopharmaceuticals approved by the U.S. Food and Drug Administration currently use a single source of agarose resins from a single manufacturing site, presenting a risk to secure, long-term clinical trial material production.

Purolite have addressed this industry-wide concern by providing a proven, reliable alternative source of agarose resins, allowing our customers to take control of their supply risk their risk by dual-sourcing their products.

Regulatory Support

Purolite Life Sciences provides customers with regulatory support documentation for *Praesto* products used by our customers in GMP regulatory environments.

Comprehensive regulatory support files are available for each *Praesto* resin, and are provided under a confidential disclosure agreement.

The purpose of this Regulatory Support File (RSF) is to provide assistance with:

- Process development of clinical and commercial purification processes
- Manufacturing validation
- Quality control tests
- Standard Operating Procedure (SOP) for cleaning in place (CIP) and sanitization
- Application for various regulatory licenses or compliance
- Plant and document audits

Quality

Global ISO 9001:2008 standards ensure consistent operating practices across each of our plants. Compliance is monitored and maintained through a quality assurance and regulatory team who conduct internal audits to ensure operations meet the guidelines and protocols for equipment and procedures. Additionally, our production team is given continual training on quality processes to ensure batch-to-batch consistency, and we host numerous customer audits each year to make sure that we are in compliance with user expectations.

Purolite maintains a global Quality Management System (QMS) which supports BSI requirements of ISO 9001:2008.

Raw Materials

Our raw material suppliers are selected and qualified from leading manufacturers and are part of our global network of suppliers. Each key raw material has at least one alternative supplier and is managed through a globally coordinated inventory system to ensure security of supply.

Additionally, a quality control protocol is in place for testing new batches/lots of raw materials to confirm product specifications and lot-to-lot consistency.

Purolite Life Sciences also has long-term supply agreements in place for our Protein A ligands, which are sourced from Repligen Corporation.

Repligen provides dual-site supply for critical raw materials and has a long-standing history of successfully supplying a variety of Protein A ligands to the industry.





100% focused on resin technology.



The world's second largest agarose manufacturing facility.



De-risked long-term supply through dual-sourcing.



25+ years of regulatory experience from FDA inspected cGMP facility.



Over 35+ years of experience in solving advanced R&D and purification challenges.

Praesto[®] 'Jetted' 35 µm High Resolution Ion Exchange Resins

Purolite is the first Agarose resin provider to produce process-scale volumes of a uniform particle size bead.

Jetting - Uniform Particle Size Beads

Jetting technology is a new patented method that produces agarose beads with a very narrow particle size distribution. Purolite is the first Agarose resin provider to produce process-scale volumes of a uniform particle size bead for the purification of recombinant proteins and monoclonal antibodies.

Jetted resins demonstrate superior performance characteristics including: increased pressure/flow properties meaning lower back pressure, improved resolution from uniform particles, improved packing reproducibility and stability, more homogenous ligand distribution, higher dynamic binding capacity, green manufacturing, the possibility to use larger mesh size column filters/nets and less risk for fouling of resin and/or supports.

Jetted Resins vs. Standard Agarose Resin Beads

- Enhanced pressure/flow properties
- Uniform particle sizes
- Increased dynamic binding capacities for high-productivity operations and easy scale-up
- Higher resolution/selectivity for demanding separations, combined with high yields
- Significantly more narrow particle size distribution. Jetted
 35 µm particle size = 95% within 25 50 µm compared to a
 35 µm standard agarose resin beads = 95% within 25 100
 µm

Figure 1. - Microscope Images







Ligand Structures

Purolite Life Sciences has commercialized highly cross linked agarose, **Praesto** SP 35 μ m (cation) and **Praesto** Q 35 μ m (anion) to provide high resolution polishing resins for recombinant proteins and other biomolecules.

Environmental Benefits

Jetted uniform beads also have several important benefits to the environment over standard agarose resin beads. Jetting technology is a continuous manufacturing process that produces beads in a more efficient way, with very high yields. Since the beads are uniform in size, it removes the need for extensive sieving, which generates considerably less waste. Another environmentally friendly advantage with this new technology is that it eliminates the need for high levels of organic solvents compared to standard agarose resin beads.

Since early 2017 Purolite was awarded ISO certification 14001:2015 for environmental management.

Pressure Flow

With new crosslinking methods, combined with jetting technology, Purolite Life Sciences have been able to develop 35 μ m small particles for improved resolution for high polishing applications that are still suitable for large scale bioprocessing. For instance, a 45 μ m standard agarose resin bead has a lower pressure flow rate capability compared to a 45 μ m jetted bead. When packed at 4 bar and ran at 3 bar, in a HiScale 26/40 (with a 2.6 cm diameter and a 20 cm BH), the 45 μ m standard agarose resin bead flow velocity reached 220 cm/h compared to the same size jetted resin (45 μ m) which reached a maximum flow velocity of 282 cm/h.

DEO	IgG DBC (10%)	IgG DBC (10%)	Flow velocity (cm/h)	
050	2.4 min	6 min	20 cm bed height	
45 (Standard)	68	97	220	
45 (Jetted)	80	108	282	

Dynamic Binding Capacity

Dynamic binding capacity is also increased with jetting technology, when compared to standard agarose resin beads. When tested at 2.4 and 6 minutes residence time, 15% high capacity results were obtained using polyclonal human IgG.



The strong ion exchange ligand groups of *Praesto* SP (a) and *Praesto* Q (b) are well established in large scale purification.

Particle Size Distribution

The particle size distribution of jetted agarose is significantly improved compared to standard agarose resin beads, e.g. a 35 μ m jetted resin bead = 95% within 25 – 50 μ m with a uniformity coefficient* of less than 1.3, compared to 45 μ m standard agarose resin bead = 95% within 25 - 100 μ m (with a uniformity coefficient of 1.9).

Figure 2. - Particle Size Distribution



*Uniformity coefficient (UC) is defined as the D60₀₀ divided by the D10₀₀.

Application Example

To demonstrate the high resolution of jetted agarose base beads over standard agarose resin base beads, we assessed the separation profiles of *Praesto* cation exchangers to reduce the acidic species using a customer-supplied biosimilar MAb. In this example, the goal was to ensure the acidic species of the biosimilar matched that of the originator. Purification with Praesto AP protein A affinity resin was followed by an anion multimodal in flow mode as the first polishing step. The material was then further purified in a bind and elution mode using two different CIEX. The first - SP 45 µm - a traditional standard agarose resin (95% within 25 - 100 μm), and a Jetted SP 35 μm, a uniform particle size agarose resin (95% within 25-50 µm, UC < 1.3). The separation profiles were assessed using a standard conductivity gradient elution.



Comparing SP 45 (standard agarose resins beads) with jetted SP 35, a far more pronounced shoulder of the acidic species can be seen on the chromatograms.

Proesto Jetted SP & Q: Typical Physical & Chemical Characteristics				
	Praesto Jetted SP	Praesto Jetted Q		
Matrix	Cross-linked agarose	Cross-linked agarose		
Functional Group	CH ₂ CH ₂ CH ₂ S03	CH ₂ N ⁺ (CH ₃) ₃		
Iconic Capacity, mmol/mL Resin	0.11-0.16	0.14-0.18		
Average Particle Size ($d_{_{50\nu}}$), µm	35	35		
Flow Velocity cm/h at 3 bar in a 2.6 x 20 cm Column (packed at 4 bar)	> 150	> 150		
Binding Capacity mg/mL Resin at 6' Residence Time	> 90 mg/ml IgG	> 80 mg/ml BSA		
Operating pH Stability (Short-term) (Long-term)	рН 3-14 рН 4-13	рН 2-14 рН 3-13		
Working Temperature	4-30°C	4-30°C		
Chemical Stability	All commonly used aqueous buffers, 1M NaOH, 8M urea, 6M guanidine hydrochloride 30% isopropanol and 70% ethanol			
Avoid	Oxidizing agents, cationic detergents	Oxidizing agents, cationic detergents		
Storage	20% ethanol, 0.2M sodium acetate, 4-30°C	20% ethanol, 4-30°C		

Praesto[®] Formats

All *Praesto* ion exchange resins are available in a variety of formats to suit your process needs, from high-throughput to full-scale commercial manufacture. Process development and up-scaling is further streamlined by using our pre-packed and pre-qualified formats.



Bulk Resins

Bulk resins are available in 10 ml, 25 ml, 100 ml, 500 ml, 1 L, 5 L and 10 L volumes. All *Praesto* Protein A resins are bottled in 20% ethanol.



HT Columns

For quick and easy separation offers pre-packed HT columns columns are available containing **Praesto** Protein A and Ion Exchange high-flow resins. The HT range of columns are available in 1 ml and 5 ml bed volumes and are compatible will all common chromatography systems.



RoboColumns®

For HTPD work, **Praesto** resins are available in RoboColumn volumes of 8 x 200 μL and 8 x 600 $\mu L.$



MiniChrom Columns

Praesto MiniChrom pre-packed columns provide a small bed volume for fast results and minimal sample and buffer consumption, as well as convenience in media screening and easy, direct connection to chromatography systems.

lon Exchange Resins Praesto® SP & Praesto Q

Highly cross-linked, agarose-based ion exchange chromatography resins for efficient protein purification, from capture to polishing. *Praesto* SP (cation) and *Praesto* Q (anion) are designed for lab to process-scale purification of recombinant proteins and other biomolecules.

Praesto SP and **Praesto** Q are available in 90 μm, 65 μm and 45 μm particle sizes, covering the use of ion exchange in high-productivity capture steps as well as high-resolution polishing applications.

Based on highly cross-linked agarose, they offer very good flow and pressure drop characteristics, excellent chemical and physical stability, high capacity, and are readily scalable.

Key Performance Benefits

- Excellent dynamic binding capacities and pressure/flow properties for high-productivity operations and easy scale-up
- High resolution/selectivity for demanding separations with high yields
- 90 µm, 65 µm and 45 µm particle sizes match the goals of capture, removal and polishing steps
- Excellent chemical and physical stability for long functional life and reduced operating costs
- Secure, validated supply and regulatory support

Figure 1: Ligand Structures

a) Praesto SP



b) Praesto Q



The strong ion exchange ligand groups of *Praesto* SP (a) and *Praesto* Q (b) are well established in large scale purification.

Figure 2A: Cation Selectivity – Capture & Intermediate Purification

Protein separation of 25 mg/ml IgG and 5 mg/ml Lactoferrin over **Praesto** SP90, Sepharose 6 Fast Flow and Capto S.

Figure 2B: Cation selectivity, intermediate & purification and polishing

Protein separation of 25 mg/ml IgG and 5 mg/ml Lactoferrin over **Praesto** SP45, **Praesto** SP65 and Capto SP ImpRes.



mAU



Figure 3A: Anion Selectivity – Capture & Intermediate Purification

Chromatograms showing the separation of α-Lactalbumin (left peak) trypsin inhibitor (right peak) **Praesto** Q90 demonstrates selectivity equal to Q Sepharose Fast Flow and Capto Q.

Figure 3B: Anion Selectivity – Intermediate Purification & Polishing

Chromatograms showing the separation of α-Lactalbumin (left peak) trypsin inhibitor (right peak) comparing *Praesto* Q45 (middle) and *Praesto* Q65 (right) with Capto Q ImpRes (left).



15 20 25 30 35

ml

10

40

35

30

25

20

15

10

5

0

40

nS/cn





With the three different particles sizes available for *Praesto* media, demands on resolution in various purification steps can be met and difficult separation challenges can be solved.

Praesto SP & Praesto Q: Typical Physical & Chemical Characteristics						
	Praesto SP		Praesto Q			
Matrix	Cross-linked agarose		Cross-linked agarose			
Functional Group	CH ₂ CH ₂ CH ₂ S03-		CH ₂ N ⁺ (CH ₃) ₃			
Iconic Capacity, mmol/mL Resin	0.11-0.16		0.14-0.18			
Average Particle Size (d _{50ν}), μm	45	65	90	45	65	90
Flow Velocity cm/h at 3 bar in a 2.6 x 20 cm Column (packed at 4 bar)	> 200	> 400	> 800	> 200	> 400	> 800
Binding Capacity mg/mL Resin at 6' Residence Time	> 80 mg > 70 mg > 50 mg IgG IgG IgG IgG		> 70 mg BSA	> 60 mg BSA	> 50 mg BSA	
Operating pH Stability (Short-term) (Long-term)	рН 3-14 рН 2-14 рН 4-13 рН 3-13					
Working Temperature	4-30°C 4-30°C					
Chemical Stability	All commonly used aqueous buffers, 1M NaOH, 8M urea, 6M guanidine hydrochloride, 30% isopropanol and 70% ethanol					
Avoid	Oxidizing agents, cationic detergents Oxidizing agents, anionic detergents			etergents		
Storage	20% ethanol, 0.2M sodium acetate, 4-30°C		20% ethanol, 4-30°C			

The table shows the general characteristics of *Praesto* ion exchangers. *Praesto* SP and *Praesto* Q are compatible with all ranges of temperature, pH and chemical and physical conditions typically used in biopharmaceutical processes. The physical and chemical stability allows cleaning with sodium hydroxide, resulting in very long functional life.

Application

Several cation exchange resins were evaluated for capacity as well as aggregate and HCP removal using two different monoclonal antibodies.

This work was performed by an independent investigator, Prof. Anurag Rathore at the Department of Chemical Engineering, Indian Institute of Technology in Delhi.

The dynamic binding capacities (DBC) at two residence times are shown in Figure 4. As expected, all resins showed higher DBC at the longer (6 minute) residence time. **Praesto** SP45, however, showed superior binding capacity for both MAbs.

Capto and Sepharose are registered trademarks of GE Healthcare.

Figure 4: DBC data for two different MAbs on various anion exchangers





Figure 4A: 5% DBC for MAb A at two residence times on Praesto SP65, Praesto SP45, Capto SP ImpRes and Capto S Impact.

Running buffer for MAb A: 20 mM sodium acetate, pH 5.5.

5% DBC data for MAb B on four resins at two different residence times.



DBC MAb at 5% break through (mg/mL of resin)

Figure 2B: 5% DBC for MAb B at two residence times on *Praesto* SP65, *Praesto* SP45, Capto SP ImpRes and Capto S Impact.

Running buffer for MAb B: 20 mM sodium acetate, pH 5.0.

Ordering Information

Ordering Information

To place your order simply contact us using the information at the bottom of this page and quote your order number from the table below.

If you wish to discuss your purification challenges with a specialist, we have dedicated experts on-hand across the globe to provide knowledgeable, same-day technical assistance.

Praesto Jetted Bulk Resin				
BULK RESIN	PACK SIZE	ORDER NUMBER		
Praesto Jetted SP35	25 ml	PR00432-166		
Praesto Jetted SP35	100 ml	PR00432-164		
Praesto Jetted SP35	500 ml	PR00432-165		
Praesto Jetted SP35	1 L	PR00432-310		
Praesto Jetted SP35	5 L	PR00432-311		
Praesto Jetted SP35	10 L	PR00432-312		
Praesto Jetted Q35	25 ml	PR00436-166		
Praesto Jetted Q35	100 ml	PR00436-164		
Praesto Jetted Q35	500 ml	PR00436-165		
Praesto Jetted Q35	1 L	PR00436-310		
Praesto Jetted Q35	5 L	PR00436-311		
Praesto Jetted Q35	10 L	PR00436-312		

Praesto Jetted HT Columns				
PRODUCT	PACK SIZE	ORDER NUMBER		
Praesto Jetted SP35 HT	5 x 1 ml*	PR00432-575		
Praesto Jetted SP35 HT	5 x 5 ml*	PR00432-576		
Praesto Jetted Q35 HT	5 x 1 ml*	PR00436-575		
Praesto Jetted Q35 HT	5 x 5 ml*	PR00436-576		

* HT columns packed with Ion Exchange resins available in packs of 5 only

Praesto SP		
BULK RESIN	PACK SIZE	ORDER NUMBER
Praesto SP45	25 ml	PR00242-166
Praesto SP45	100 ml	PR00242-164
Praesto SP45	500 ml	PR00242-165
Praesto SP45	1 L	PR00242-310
Praesto SP65	25 ml	PR00262-166
Praesto SP65	100 ml	PR00262-164
Praesto SP65	500 ml	PR00262-165
Praesto SP65	1 L	PR00262-310
Praesto SP90	25 ml	PR00292-166
Praesto SP90	100 ml	PR00292-164
Praesto SP90	500 ml	PR00292-165
Praesto SP90	1 L	PR00292-310
PRE-PACKED COLUMNS		
Praesto SP45 MiniChrom (8 x 20 mm)	1 x 1 ml	PR00242-175
Praesto SP65 MiniChrom (8 x 20 mm)	1 x 1 ml	PR00262-175
Praesto SP90 MiniChrom (8 x 20 mm)	1 x 1 ml	PR00292-175
Praesto SP45 MiniChrom (8 x 100 mm)	1 x 5 ml	PR00242-176
Praesto SP65 MiniChrom (8 x 100 mm)	1 x 5 ml	PR00262-176
Praesto SP90 MiniChrom (8 x 100 mm)	1 x 5 ml	PR00292-176
Praesto SP45 RoboColumn® (5 x 10 mm)	8 x 200 μl	PR00242-174
Praesto SP65 RoboColumn® (5 x 10 mm)	8 x 200 μl	PR00262-174
Praesto SP90 RoboColumn® (5 x 10 mm)	8 x 200 μl	PR00292-174

Praesto SP Continued				
PRE-PACKED COLUMNS				
Praesto SP45 HT Column	5 x 1 ml*	PR00242-575		
Praesto SP45 HT Column	5 x 5 ml*	PR00242-576		
Praesto SP65 HT Column	5 x 1 ml*	PR00262-575		
Praesto SP65 HT Column	5 x 5 ml*	PR00262-576		
Praesto SP90 HT Column	5 x 1 ml*	PR00292-575		
Praesto SP90 HT Column	5 x 5 ml*	PR00292-576		

 \star HT columns packed with Ion Exchange resins available in packs of 5 only.

Praesto Q		
BULK RESIN	PACK SIZE	ORDER NUMBER
Praesto Q45	25 ml	PR00246-166
Praesto Q45	100 ml	PR00246-164
Praesto Q45	500 ml	PR00246-165
Praesto Q45	1 L	PR00246-310
Praesto Q65	25 ml	PR00266-166
Praesto Q65	100 ml	PR00266-164
Praesto Q65	500 ml	PR00266-165
Praesto Q65	1 L	PR00266-310
Praesto Q90	25 ml	PR00296-166
Praesto Q90	100 ml	PR00296-164
Praesto Q90	500 ml	PR00296-165
Praesto Q90	1 L	PR00296-310

Praesto Q Continued				
PRE-PACKED COLUMNS				
Praesto Q45 MiniChrom (8 x 20 mm)	1 x 1 ml	PR00246-175		
Praesto Q65 MiniChrom (8 x 20 mm)	1 x 1 ml	PR00266-175		
Praesto Q90 MiniChrom (8 x 20 mm)	1 x 1 ml	PR00296-175		
Praesto Q45 MiniChrom (8 x 100 mm)	1 x 5 ml	PR00246-176		
Praesto Q65 MiniChrom (8 x 100 mm)	1 x 5 ml	PR00266-176		
Praesto Q90 MiniChrom (8 x 100 mm)	1 x 5 ml	PR00296-176		
Praesto Q45 RoboColumn [®] (5 x 10 mm)	8 x 200 μl	PR00246-174		
Praesto Q65 RoboColumn [®] (5 x 10 mm)	8 x 200 μl	PR00266-174		
Praesto Q90 RoboColumn® (5 x 10 mm)	8 x 200 μl	PR00296-174		
Praesto Q45 HT Column	5 x 1 ml*	PR00246-575		
Praesto Q45 HT Column	5 x 5 ml*	PR00246-576		
Praesto Q65 HT Column	5 x 1 ml*	PR00266-575		
Praesto Q65 HT Column	5 x 5 ml*	PR00266-576		
Praesto Q90 HT Column	5 x 1 ml*	PR00296-575		
Praesto Q90 HT Column	5 x 5 ml*	PR00296-576		

The Praesto® Range

The **Praesto** range offers a selection of modern, high-flow Affinity and Ion Exchange agarose resins, delivering exceptional results from Protein A to high-resolution polishing steps. The range also includes a full selection of **Praesto** Pure base matrices, and pre-activated resins in a variety of source chemistries.

All **Praesto** products provide an advanced, high-flow, highly cross-linked agarose base matrix. The entire range benefits from excellent pressure/flow characteristics and stability for optimal recovery of active proteins.

Discover Praesto at: www.purolite.com/life-sciences

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