Praesto®

IEX Chromatography Resins

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

Purolite®

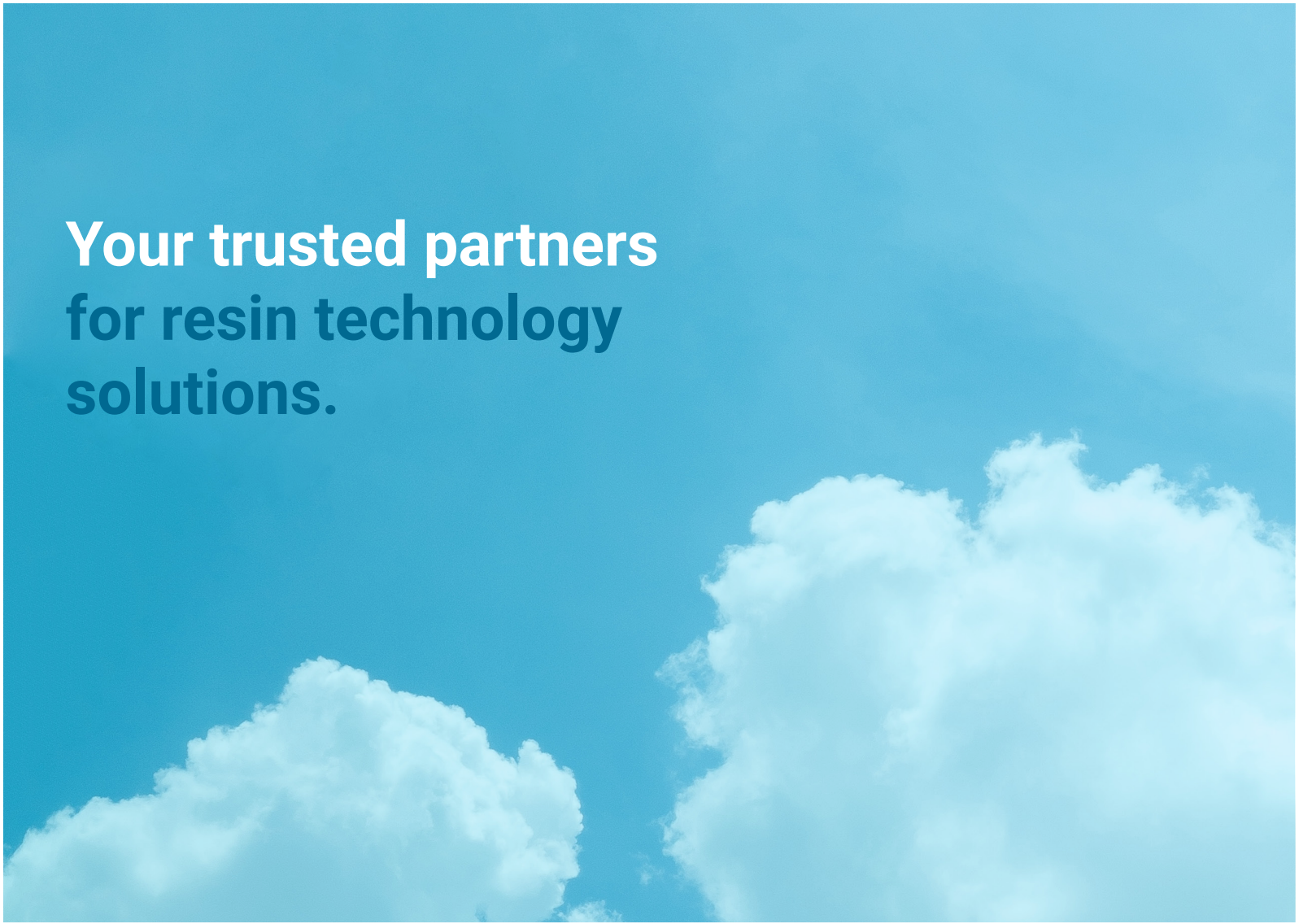
Since 1981, Purolite® has grown into the world's premier resin-based separation, purification and extraction technology manufacturer and innovation leader, with manufacturing facilities, advanced research laboratories and over 1400 people employed world-wide.

Your solutions company

Purolite® focuses on any applications involving interactions with people, bringing innovative thinking and a distinguished history of resin technology expertise to the global Life Sciences marketplace.

We supply premium quality APIs, enzyme carriers, immobilized enzymes, and agarose or synthetic chromatography resins for purification and separation, to support research and development and production-scale applications in pharmaceuticals, protein purification, food processing, bioprocessing and fine chemical markets.

“We provide solutions for our customers’ most critical questions.”


Your trusted partners
for resin technology
solutions.

100% focused on resin technology - with one of the largest agarose manufacturing facilities in the world.


Purolite®
“For over 40 years Purolite has supplied specialty ion exchange resin technology to industries within complex regulatory environments.”

Introduction

For over 40 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.

Praesto ion exchange resins are designed for biomolecule purification, including proteins, peptides and oligonucleotides.

Key features

90 µm, 65 µm and 45 µm particle sizes match the goals of capture, removal and polishing steps

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

Supplied in bulk or in pre-packed, pre-qualified OPUS® columns from Repligen Corporation

Secure, validated supply and regulatory support

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.

Praesto products are also available pre-packed in OPUS® columns from Repligen Corporation.

The perfect choice for screening, sample preparation, and process validation through scale-up and commercial manufacturing.

Ligand Structure

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

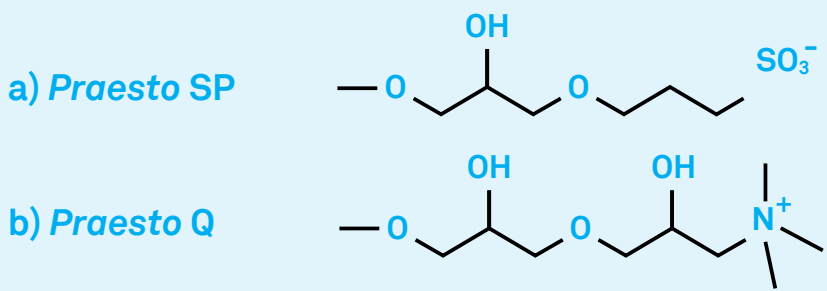


Figure 1. Ion structure of Praesto SP and Praesto Q

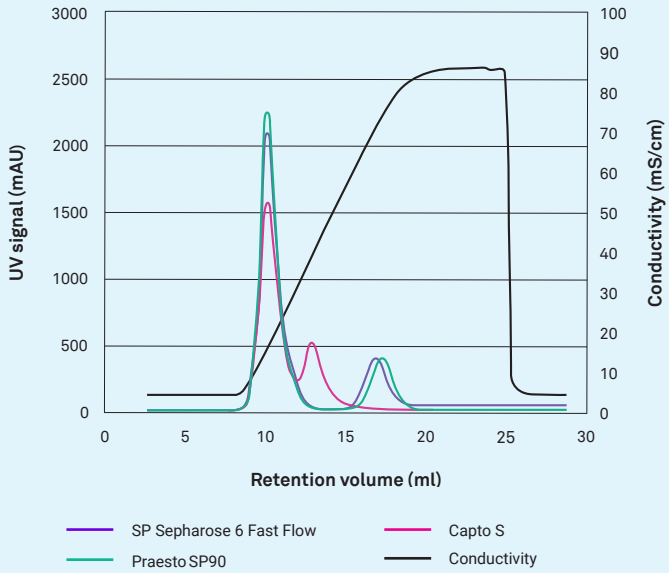
Praesto SP & Q

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.

Performance
Data



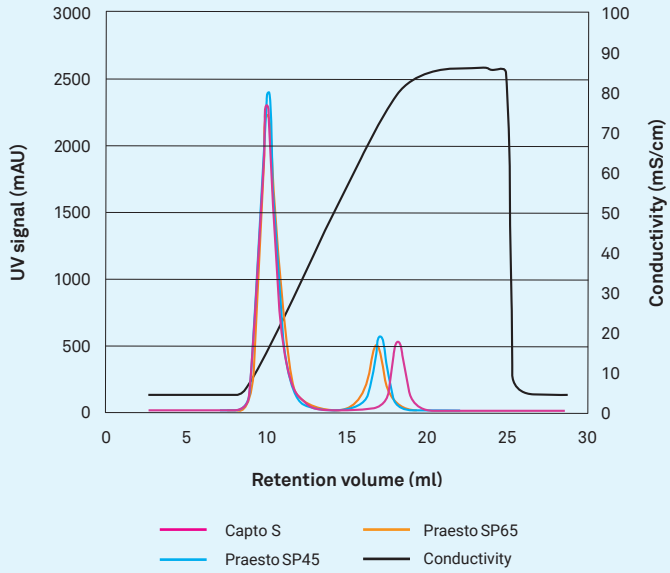


Figure 2A: Cation Selectivity – Capture & Intermediate Purification Protein separation of 25 mg/ml IgG and 5 mg/ml Lactoferrin over Praesto SP90, Sepharose 6 Fast Flow and Capto S.
Figure 2B: Cation selectivity, intermediate & purification and polishing, Protein separation of 25 mg/ml IgG and 5 mg/ml Lactoferrin over Praesto SP45, Praesto SP65 and Capto SP ImpRes.

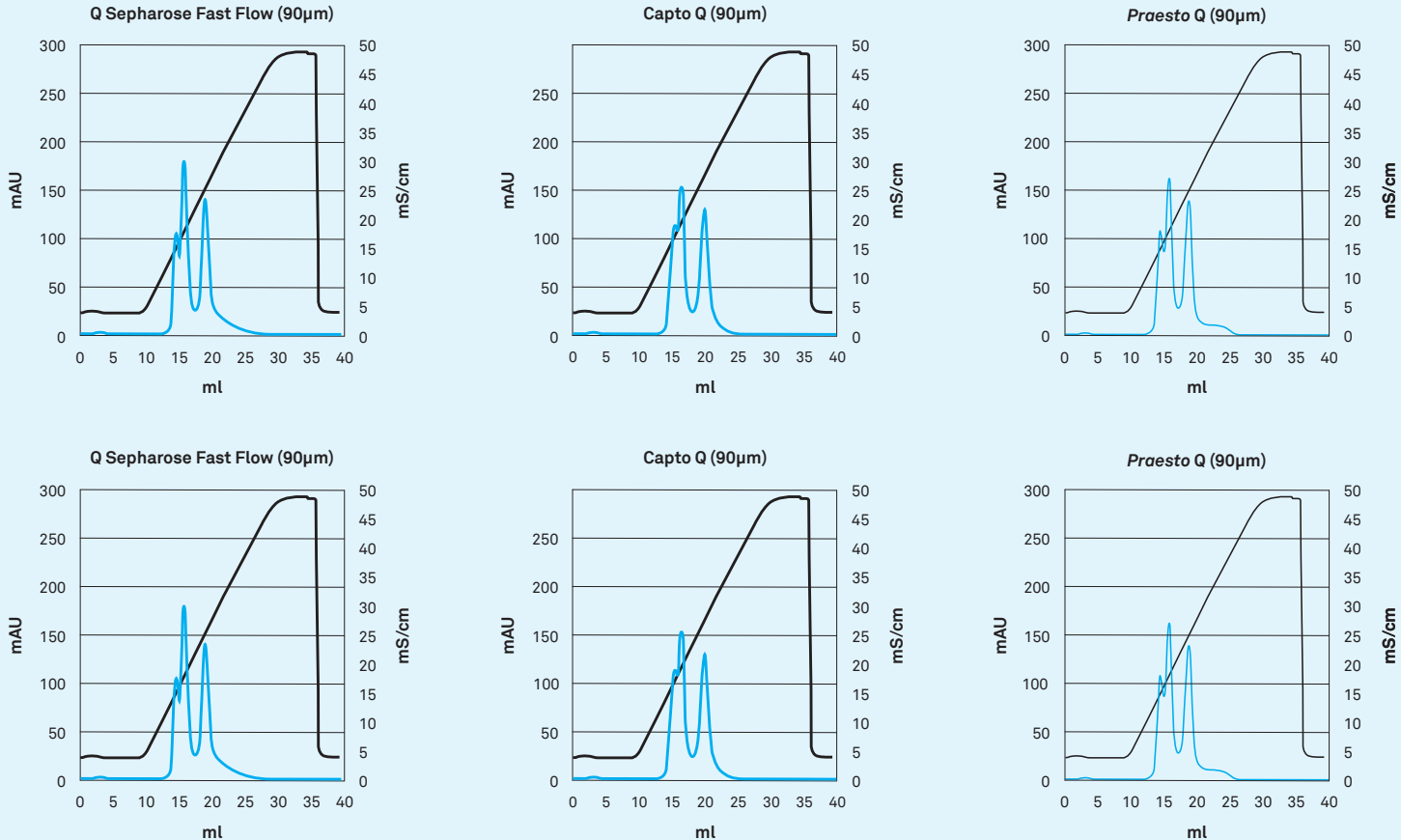


Figure 3A: Cation Selectivity – Capture & Intermediate Purification Protein separation of 25 mg/ml IgG and 5 mg/ml Lactoferrin over Praesto SP90, Sepharose 6 Fast Flow and Capto S.

Figure 3B: 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.

Typical Physical & Chemical Characteristics

	Praesto SP			Praesto Q		
Matrix	Cross-linked agarose			Cross-linked agarose		
Functional Group	$CH_2CH_2CH_2S03$-			$CH_2N^+(CH_3)_3$		
Ionic Capacity, mmol/mL Resin	0.11-0.16			0.14-0.18		
Average Particle Size (d_{50v}), µm	45	65	90	45	65	90
Flow Velocity cm/h at 3 bar in a 2.6x 20 cm Column (packed at 4 bar)	> 200	> 400	> 800	> 200	> 400	> 800
Binding Capacity mg/mL Resin at 6' Residence Time	> 80mg IgG	> 70 mg IgG	> 50 mg IgG	> 70 mg BSA	> 60 mg BSA	> 50 mg BSA
Operating pH Stability (short-term) (long-term)	pH 3-14 pH 4-13			pH 2-14 pH 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		

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.

5% DBC data for mAb A on four resins at two different residence times

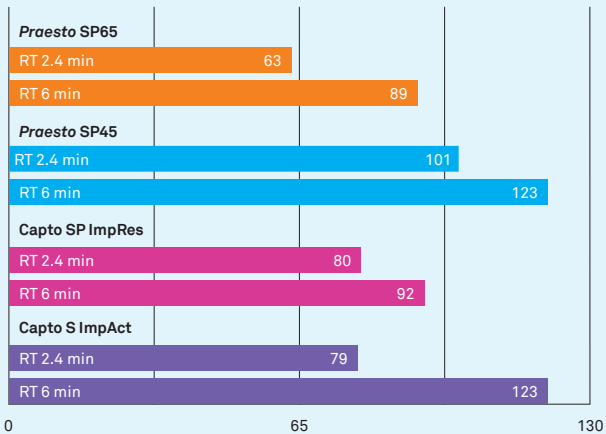


Figure 4A: 5% for mAb A at two residence times on Praesto SP65, Praesto SP45, Capto SP ImpRes and Capto S Impact

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

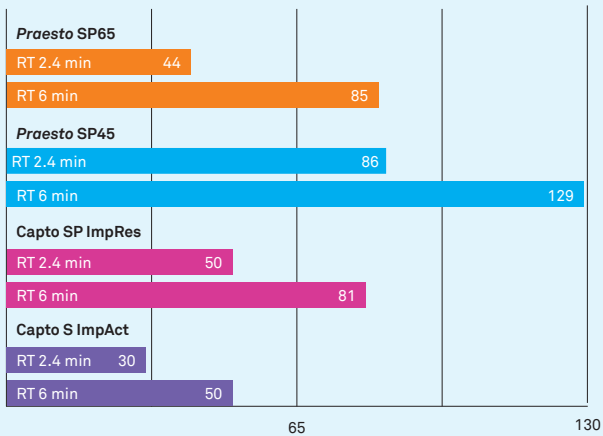


Figure 4B: 5% DBC for mAb A at two residence times on Praesto SP65, Praesto SP45, Capto SP ImpRes and Capto S Impact

Running buffer for mAb A: 20 mM sodium acetate, pH 5.0.

*Capto and Sepharose are registered trademarks of GE Healthcare


Stability from
a robust supply
chain

Complete regulatory support

For over 40 years, Purolite has supplied specialty resin technology to industries within complex regulatory environments including biotechnology, pharmaceutical, food, fine chemical and electric power generation.

The regulatory environment is ever changing, driven by increasing regulatory requirements, increasing development costs and times, and market pressures impacting pharmaceutical and food industries.

For Healthcare & Life Sciences products, Regulatory Support Files (RSF) are available. Regulatory Support Files provide direct and detailed information on performance, stability, extractable compounds, and analytical methods for each resin.

“Regulatory expertise throughout the product life-cycle is essential to identify options for product development, optimize ‘speed to market’ and produce a product that meets customer needs.”

Purolite implements control documentation and processes at every level to ensure regulatory support to customers using our products.

Purolite complies with required national and international regulations, as well as many voluntary specialty certifications.

These include:

- GMO/TSE/BSE free
- ISO 9001:2015 quality system specifications
- ISO 14001:2015 Environmental Management System requirements

We also hold Drug Master Files with the US FDA, Japan, Canada and EU


Security of supply
Lot-to-lot consistency
Consistent operating practices across sites
Internal audits
Continual quality training
Compliant containers
Certificates of analysis (CoA)
Raw material supplier program

Quality

Purolite maintains a global Quality Management System (QMS) which supports BSI requirements of ISO 9001. 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. Our teams are given continuous training on quality processes to ensure batch-to-batch consistency, and the highest product quality.

Secure Supply through Manufacturing Excellence

Ensuring reliable availability of our resins is vital to customers, and of paramount importance to Purolite. As a leading supplier of resin to the world's most regulated industries, we recognize that our resins are critical purification products. As such, a real-world security-of-supply system is in place to support your process requirements for business continuity.

Supply risk is managed end-to-end, with a global network of qualified suppliers. Long-term supply agreements with periodic audits ensure consistency and 'fit for purpose' performance.

Purolite has manufacturing facilities at 4 strategic locations in the USA, Asia and Europe, including the recent addition of one of the world's largest agarose resin manufacturing facilities located in Llantrisant, South Wales, UK.

Our agarose manufacturing facility includes state-of-the-art Siemens® automation systems and can securely supply 30% of the current annual global demand for agarose chromatography resins to the biopharmaceutical sector.

Our Romanian facility is FDA-inspected, with a total of 4 state-of-the-art clean rooms. These offer separate facilities for ligand/enzyme immobilization, removal of fines, solvent or purified water washing, screening, vacuum drying and packaging. Lifetech™ and Chromalite® products are manufactured in a clean room dedicated solely to Life Sciences products.

Safety data

Purolite maintains Material Safety Data Sheets (MSDS for the U.S. and ERSDS for Europe) on all of its bulk resins. These data sheets contain relevant information that you may need to protect your customers and employees against any known health or safety hazards associated with our products.

Purolite supplies copies of our Material Safety Data Sheets with all bulk resins. These describe precautions to be taken in the storage and handling of our products and in the maintenance of the health and safety of persons exposed to our products, the public and the environment with respect to our products.


Purolite®

Placing your order

How to order

To place your order simply contact us via email or telephone using the information on the next page, and quote your order number from the table below.

If you would like to discuss how Praesto IEX resins can benefit your process, we have dedicated experts on-hand across the globe to provide knowledgeable, same-day technical assistance.

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

Praesto SP Pre-Packed Columns

BULK RESIN	PACK SIZE	ORDER NUMBER
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 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 1 ml*	PR00292-576

** 1 ml 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 Columns

BULK RESIN	PACK SIZE	ORDER NUMBER
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 1 ml*	PR00296-576

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

100% focused on resin technology.

Global manufacturing at facilities in the UK, Romania, China and USA.

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

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

Over 40 years of experience in solving advanced R&D and purification challenges.

Purolite brings innovative thinking and distinguished history of resin technology expertise to the global Life Sciences marketplace.

Over tfour decades, Purolite has grown into the world's premier resin technology manufacturer and innovation leader, with production plants and advanced research labs across the globe.

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