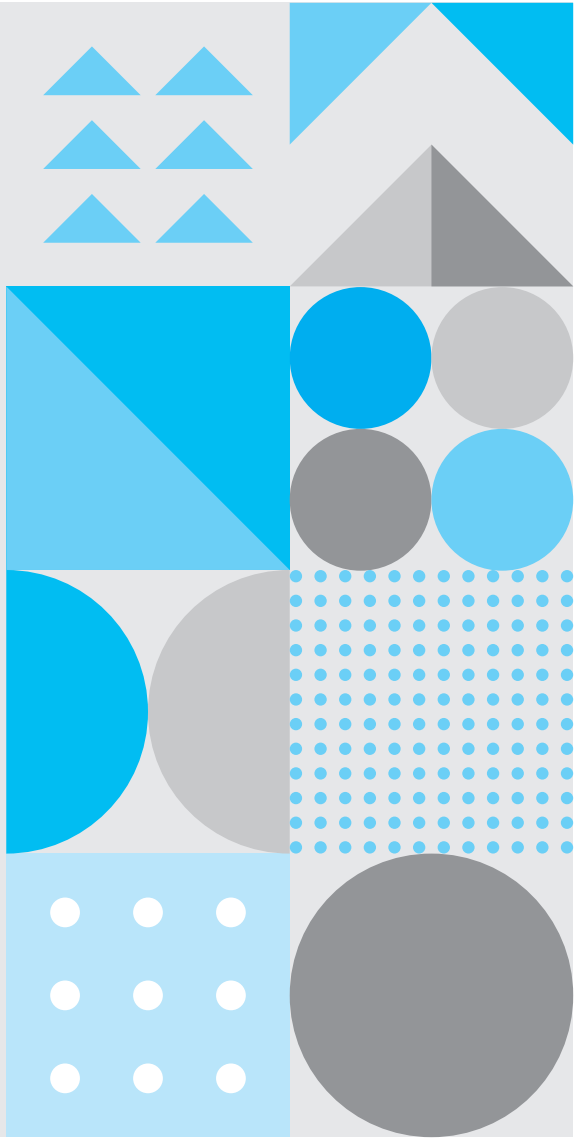
Praesto®

Protein A Resins

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



Purolite®
Life Sciences

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.

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

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.

Key features

100% focused on resin technology.

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

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.

“Purolite Life Sciences 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.

Historically, approximately 90% of all biopharmaceuticals approved by the U.S. Food and Drug Administration utilized a single source of agarose resins from a single manufacturing site, presenting a security of supply risk to wlong-term clinical trial material production.

Purolite have addressed this industry-wide concern by providing the first proven and reliable alternative source of agarose resins, allowing customers to dual-source their products to mitigate their supply risks.

Purolite has manufacturing facilities at 4 strategic global locations in the USA, Asia and Europe. Our UK-based manufacturing facility utilizes state-of-the-art Siemens® automation systems and can securely supply 30% of current annual global demand for agarose-based chromatography resins to the biopharmaceutical sector.

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:

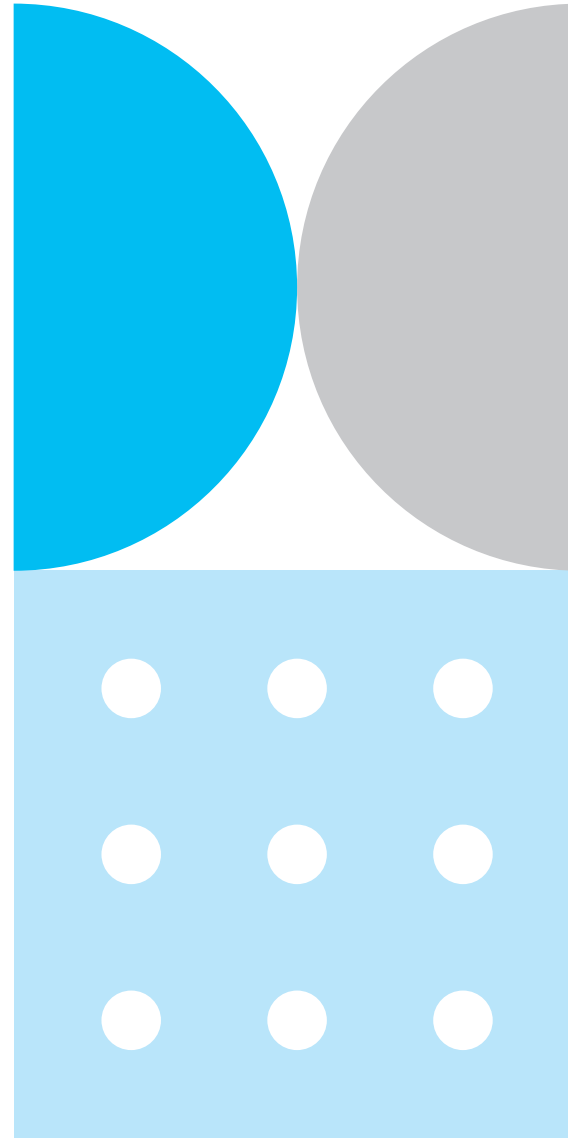
- Process development of clinical and commerical purification processes
- Manufacturing validation
- Quality control tests
- Standard Operating Procedure (SOP) for cleaning in place (CIP) and sanitization
- Application for various regulatory licenses or compliance
- Plant and document audits

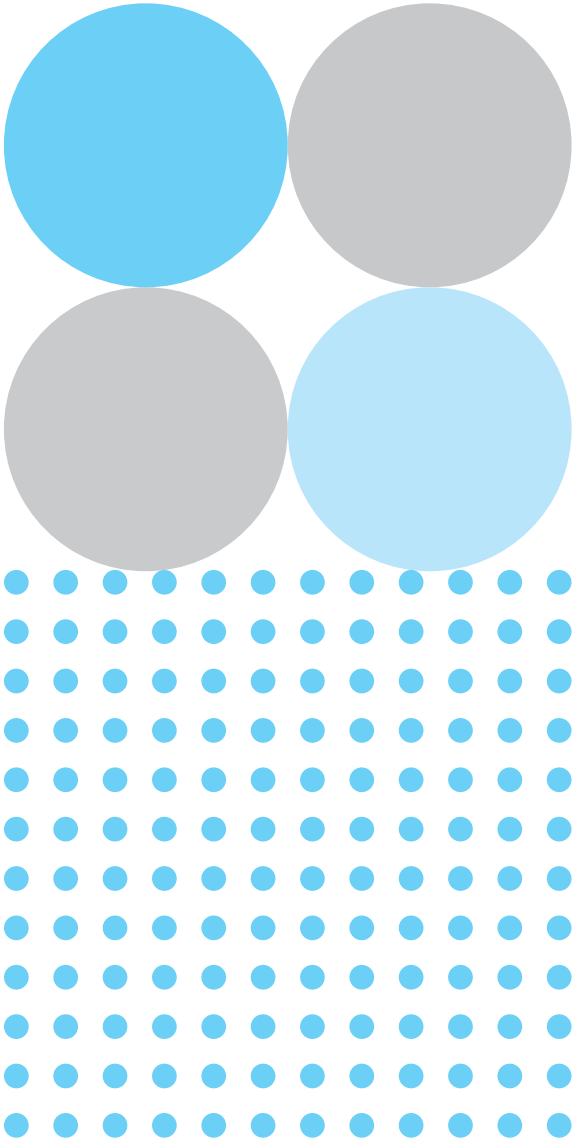
Quality

Global ISO 9001:2015 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 9001:2015.





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.

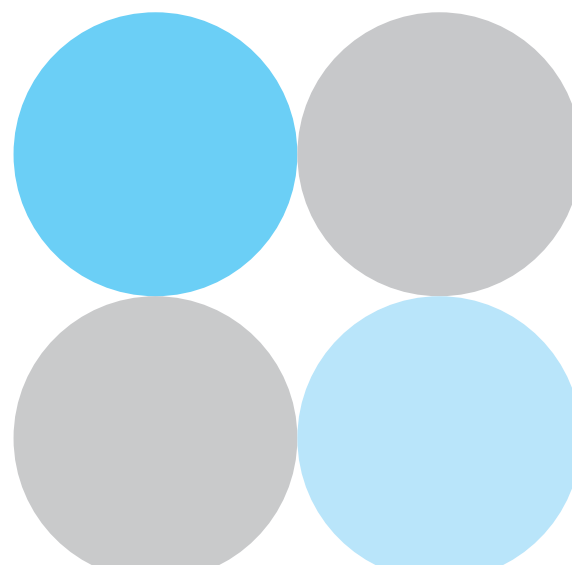
Repligen provides dual-site supply for critical raw materials and has a long-standing history of successfully supplying a variety of Protein A ligands to the industry.

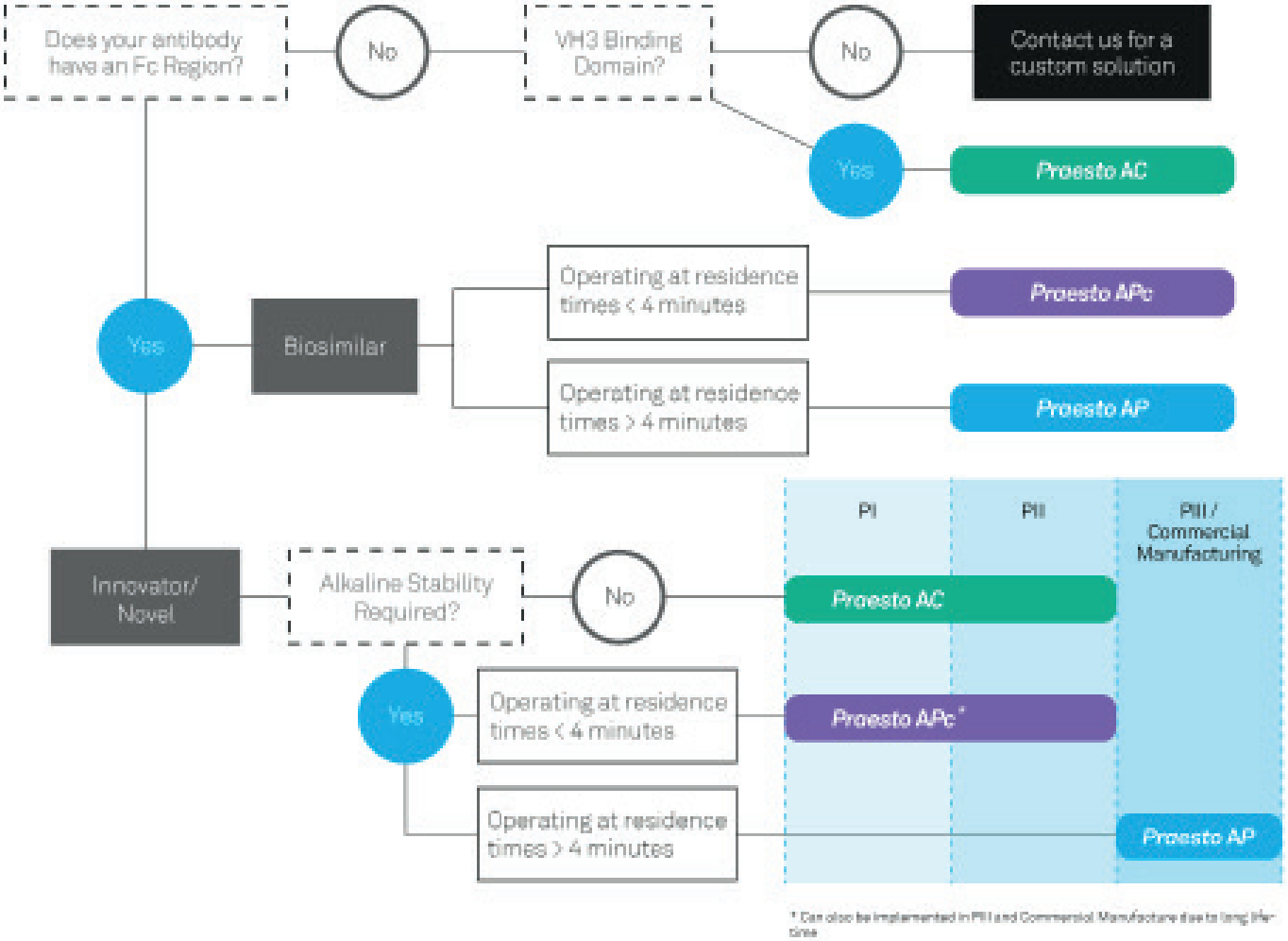

Reduce your clinical trial costs
by up to 65% using *Praesto*
resins

Production of early phase (PI & PII) clinical trial material can be very costly when balanced against high failure rates. Much of this unnecessary expense results from utilizing Protein A resins optimized for 100+ cycles when, typically fewer than 20 purification cycles are performed.

One method of maximizing your cost efficiencies is to follow Purolite Life Sciences' recommended strategy of switching Protein A resins after PII, only utilizing a higher-cost resin optimized for 100+ cycles when your process requirements justify your cost of goods.

Our selection of highly-optimized Protein A resins deliver the highest possible performance. Follow our Protein A resin selection guide to find your ideal Praesto Protein A resin.




Does your antibody have an Fc Region?
No
VH3 Binding Domain?
No
Contact us for a custom solution
Yes
Proesto AC
Yes
Biosimilar
Operating at residence times < 4 minutes
Proesto APc
Operating at residence times > 4 minutes
Proesto AP
Innovator/ Novel
Alkaline Stability Required?
No
Proesto AC
Yes
Operating at residence times < 4 minutes
Proesto APc*
Operating at residence times > 4 minutes
Proesto AP
PI
PII
PIII/ Commercial Manufacturing
* Can also be implemented in PII and Commercial Manufacture due to long lifetimes

Protein A Resins

Praesto APc & Praesto AP

Modern, high flow agarose-based,
alkaline-stable Protein A resins for
cost-effective, high productivity MAb capture.

Praesto Protein A Resins

Purolite Life Sciences has designed two alkaline-stable Protein A resins - Praesto APc and Praesto AP.

Both Praesto APc and Praesto AP are based on the same 85 µm agarose base matrix and identical Protein A ligand, differing only in the amount of Protein A immobilization required.

Praesto APc provides high capacities of over 40 mg/ml, at 4 minutes residence time. It is purpose-designed and evaluated for phase I and II clinical trials - where typically less than 20 reuse cycles are performed - but Praesto APc can be implemented across all phases due to long life time.

Praesto AP provides ultra-high capacities of over 50 mg/ml, particularly at residence times of 6 minutes or higher. It is purpose-designed and evaluated for the production of late phase clinical trial material and commerical manufacture, where typically hundreds of reuse cycles are performed.

Key Performance Benefits

- Reduces volume required and overall process times with ultra-high capacities
- Increased throughput due to excellent pressure/flow performance
- Long lifetime due to alkaline-tolerant, modified Protein A
- Minimize non-specific binding due to hydrophilic agarose base matrix
- Minimal Protein A leaching via multi-point attachment
- Up to 50% cost savings compared to MabSelect™ SuRe/LX

Praesto Protein A Ligand

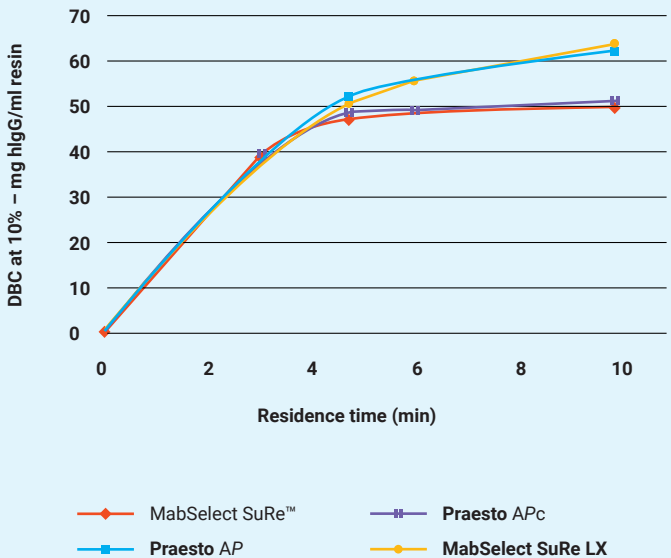
The novel, alkaline-tolerant Protein A ligand was developed through protein engineering of a Protein A IgG-binding domain. The improved alkaline-stability permits the use of sodium hydroxide for CIP and sanitization whilst still achieving a functional lifetime of 100s of purification cycles.

Supply Agreement

The Protein A ligand is provided under a supply agreement with Repligen Corporation, with the production process free from sources of mammalian origin.

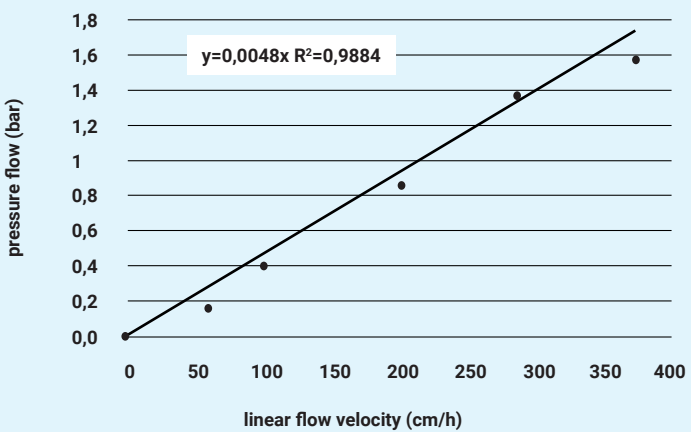
Performance
Data

Dynamic Binding Capacity

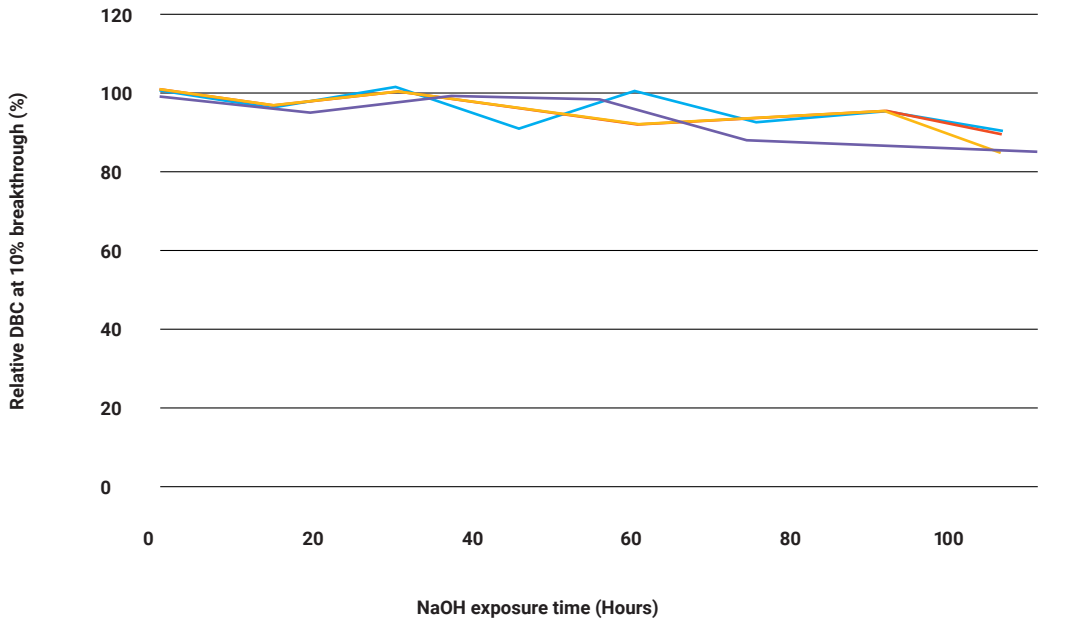


Pressure/Flow Performance

The Praesto high flow agarose base matrix provides a rigid, but open pore structure. This results in high productivities due to the ability to operate at high flow velocities at process-scale, compared to softer, cross-linked agarose resins with similar porosity.



Dynamic Binding Capacity After Cleaning In Place - 0.1 M NaOH



Protein A Leakage

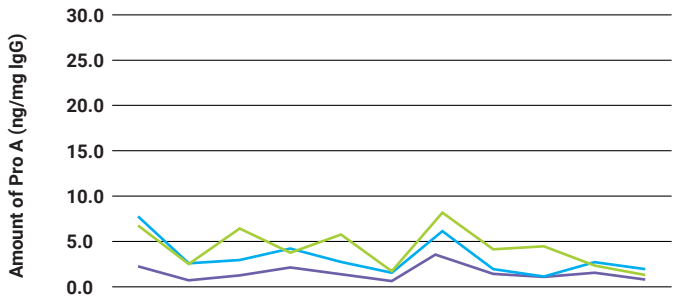
Protein A leakage occurs during:

- NaOH exposure
- Exposure to protease containing cell culture supernatants
- Spontaneous deamidation

The use of multipoint-attached alkaline-stable Praesto Protein A resins has a positive impact on each of these challenging factors.

The figure on the right shows Protein A eluate levels assayed during a re-use study over 20 cycles.

The results are consistently below 10 mg Protein A/ mg IgG in all twenty product pools. The feed stock was kindly provided by Alvotech Biopharmaceuticals.



	1	2	4	6	8	10	12	14	16	18	20
AP	2.2	0.7	1.3	2.1	1.4	0.6	3.5	1.4	1.1	1.5	0.8
APc	7.8	2.6	3.0	4.2	2.9	1.5	6.1	2.0	1.2	2.7	2.0
AC	6.8	2.5	6.4	3.8	5.8	1.7	8.1	4.1	4.4	2.4	1.3

Praesto AP & APc: Typical Physical & Chemical Characteristics		
	Praesto AP	Praesto APc
Application	MAb capture	
Polymer Structure	Highly cross linked agarose	
Appearance	Spherical beads	
Functional Group	Recombinant Protein A (E. coli)	
Dynamic Binding Capacity	>50 mg hIgG/mL resin at 4 minutes residence time[1]	>40 mg hIgG/mL resin at 4 minutes residence time[1]
Average Particle Size[2]	85 µm	
Pressure/Flow Specifications	> 500 cm/h at 3 bar in a 2.6 x 20 cm column	
pH Stability, Working Range	3 - 10	
pH Stability, CIP (Short-term)	2 - 13.7[3]	
Recommended Storage	2 to 8°C, 20% ethanol, supplied in 20% ethanol	

[1] Determined at 10% breakthrough by frontal analysis in a column with a bed height of 20 cm.

[2] $d_{50}v$ is the median particle size of the cumulative volume distribution.

[3] pH below 3 may be required to elute strongly bound species, but protein ligands can hydrolyse at very low pH.

Protein A Resins

Praesto AC

Modern agarose-based Protein A affinity resin for cost-effective, high productivity MAb capture, designed to address today's early-phase clinical manufacturing challenges.

Praesto AC

Praesto AC is purpose-designed and evaluated for production of early phase clinical trial material, where typically less than 20 cycles are run.

With capacity over 40 mg/mL at 4 minutes residence time or higher, Praesto AC combines high capacity, excellent pressure/flow performance, and NaOH CIP stability for over 20 cycles, thus meeting the common requirements for production of materials for PI and PII clinical trials. It is an excellent choice for the capture step in a typical MAb platform process.

Praesto AC can also be used in small scale MAb purification, in purification of MAbs for diagnostics, in process development and in pre-clinical processes.

Key Performance Benefits:

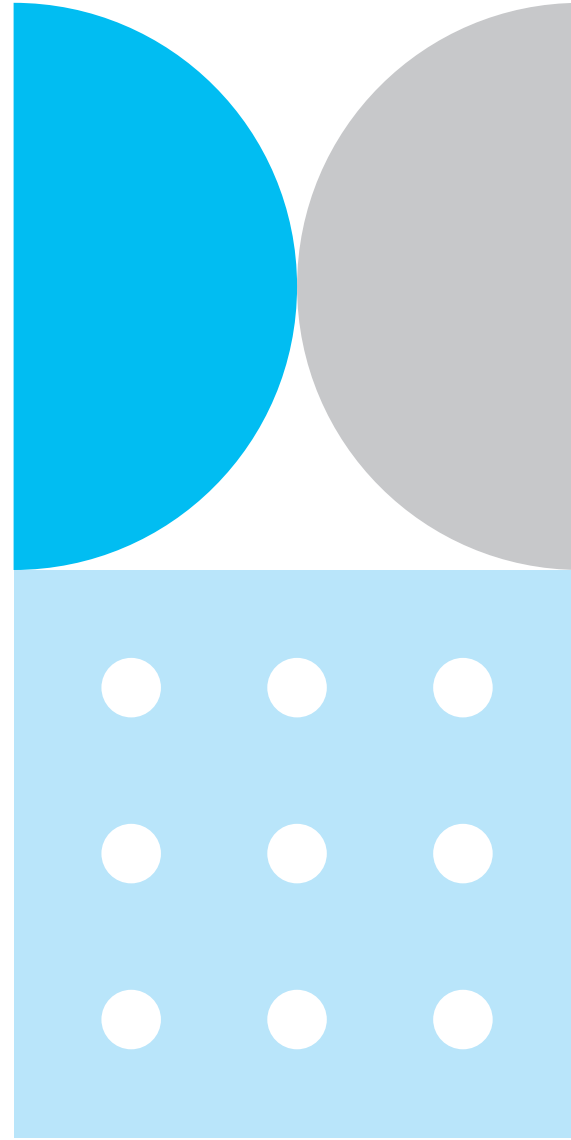
- Reduces volume required and overall process times with ultra-high capacities
- Increased throughput due to excellent pressure/flow performance
- Long lifetime due to alkaline-tolerant, modified Protein A
- Minimal Protein A leaching via multi-point attachment
- Up to 65% cost savings compared to MabSelect SuRe

Production of Early-Phase Clinical Material

Despite platform approaches to MAb processing, the production of materials for early-phase clinical trials can be costly.

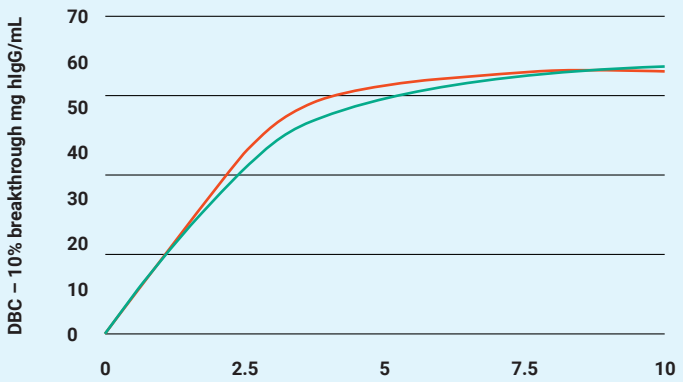
Much of the expense comes from using the same purification tools that are used later for many cycles in full scale production. Particularly for more expensive resins like Protein A, the cost/cycle or cost/g product looks prohibitive when the resin is used for only a few cycles in clinicals production, instead of the 100s of cycles it is designed for.

Praesto AC is an example of a purpose-designed resin, specified and evaluated for production of early-phase clinical trial material. It delivers both process and cost efficiencies.



Performance
Data

Dynamic Binding Capacity

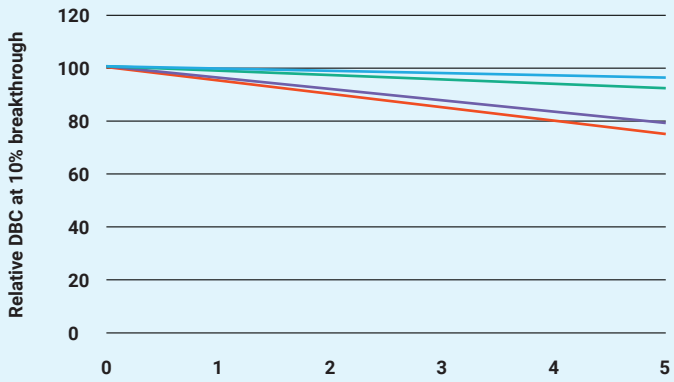


DBC at 10% breakthrough at various residence times measured with a 5 mg hIgG/mL solution, pH 7.4

MabSelect SuRe™

Praesto AC

Dynamic Binding Capacity After Cleaning In Place - 0.1 M NaOH and 0.5 M NaOH



NaOH exposure time (h)

CIP study over 5 hour exposure time using 0.1 M and 0.5 M NaOH. DBC measured with a 5 mg hIgG/mL solution, pH 7.4.

0.1 M MabSelect

0.5 M MabSelect

0.1 M Praesto AC

0.5 M Praesto AC

Praesto® Formats

All Praesto 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 pre-packed HT 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 with all common chromatography systems.

Praesto® Formats Continued...

RoboColumns®

For HTPD work, Praesto resins are available in RoboColumn volumes of 8 x 200 uL and 8 x 600 uL. They are 100% quality checked for HETP and asymmetry.

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. They are 100% quality checked for HETP and asymmetry.

Praesto AC: Typical Physical & Chemical Characteristics	
Application	MAb capture
Polymer Structure	Highly cross linked agarose
Appearance	Spherical beads
Functional Group	Recombinant Protein A (E. coli)
Dynamic Binding Capacity	>40 mg hIgG/mL resin at 4 minutes residence time[1]
Average Particle Size[2]	85 µm
Pressure/Flow Specifications	> 500 cm/h at 3 bar in a 2.6 x 20 cm column
pH Stability, Working Range	3 - 10
pH Stability, CIP (Short-term)	2 - 13[3]
Recommended Storage	2 to 8°C, 20% ethanol, supplied in 20% ethanol

[1] Determined at 10% breakthrough by frontal analysis in a column with a bed height of 20 cm.

[2] $d_{50}v$ is the median particle size of the cumulative volume distribution.

[3] pH below 3 may be required to elute strongly bound species, but protein ligands can hydrolyse at very low pH.

Placing your order

How to order

To place your order simply contact us via email or telephone using the information on the Contact Information page in this brochure 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® APc Ordering Information

BULK RESIN	PACK SIZE	ORDER NUMBER
Praesto® APc	10 ml	PR00310-163
Praesto® APc	25 ml	PR00310-166
Praesto® APc	100 ml	PR00310-164
Praesto® APc	500 ml	PR00310-165
Praesto® APc	1 L	PR00310-310
Praesto® APc	5 L	PR00310-311
Praesto® APc	10 L	PR00310-312
PRE-PACKED COLUMNS	**PACK SIZE**	**ORDER NUMBER**
Praesto® APc MiniChrom Column (8 x 20 mm)	1 x 1 ml	PR00310-175
Praesto® APc MiniChrom Column (8 x 100 mm)	1 x 5 ml	PR00310-176
Praesto® APc RoboColumn (5 x 10 mm)	8 x 200 µl	PR00310-174
Praesto® APc RoboColumn (5 x 30 mm)	8 x 600 µl	PR00310-279
Praesto® APc HT Column	1 ml	PR00310-275
Praesto® APc HT Column	5 x 1 ml	PR00310-575
Praesto® APc HT Column	5 ml	PR00310-276
Praesto® APc HT Column	5 x 5 ml	PR00310-576

Praesto® AP Ordering Information

BULK RESIN	PACK SIZE	ORDER NUMBER
Praesto® AP	10 ml	PR00300-163
Praesto® AP	25 ml	PR00300-166
Praesto® AP	100 ml	PR00300-164
Praesto® AP	500 ml	PR00300-165
Praesto® AP	1 L	PR00300-310
Praesto® AP	5 L	PR00300-311
Praesto® AP	10 L	PR00300-312
PRE-PACKED COLUMNS	**PACK SIZE**	**ORDER NUMBER**
Praesto® AP MiniChrom Column (8 x 20 mm)	1 x 1 ml	PR00300-175
Praesto® AP MiniChrom Column (8 x 100 mm)	1 x 5 ml	PR00300-176
Praesto® AP RoboColumn (5 x 10 mm)	8 x 200 µl	PR00300-174
Praesto® AP RoboColumn (5 x 30 mm)	8 x 600 µl	PR00300-279
Praesto® AP HT Column	1 ml	PR00300-275
Praesto® AP HT Column	5 x 1 ml	PR00300-575
Praesto® AP HT Column	5 ml	PR00300-276
Praesto® AP HT Column	5 x 5 ml	PR00300-576

Praesto® AC Ordering Information

BULK RESIN	PACK SIZE	ORDER NUMBER
Praesto® AC	10 ml	PR00200-163
Praesto® AC	25 ml	PR00200-166
Praesto® AC	100 ml	PR00200-164
Praesto® AC	500 ml	PR00200-165
Praesto® AC	1 L	PR00200-310
Praesto® AC	5 L	PR00200-311
Praesto® AC	10 L	PR00200-312
PRE-PACKED COLUMNS	**PACK SIZE**	**ORDER NUMBER**
Praesto® AC MiniChrom Column (8 x 20 mm)	1 x 1 ml	PR00200-175
Praesto® AC MiniChrom Column (8 x 100 mm)	1 x 5 ml	PR00200-176
Praesto® AC RoboColumn (5 x 10 mm)	8 x 200 µl	PR00200-174
Praesto® AC RoboColumn (5 x 30 mm)	8 x 600 µl	PR00200-279
Praesto® AC HT Column	1 ml	PR00200-275
Praesto® AC HT Column	5 x 1 ml	PR00200-575
Praesto® AC HT Column	5 ml	PR00200-276
Praesto® AC HT Column	5 x 5 ml	PR00200-576

Contact information

Americas
150 Monument Road
Bala Cynwyd, PA
19004

T +1 800.343.1500
T +1 610.668.9090
F -+1 484.384.2751

Americas@purolite.com

Europe
Llantrisant Business Park
Llantrisant
Wales, UK
CF72 8LF

T +44 1443 229334
F +44 1443 227073

Europe@purolite.com

Asia Pacific
Room 707, C Section
Huanglong Century Plaza
No.3 Hangda Road
Hangzhou, Zhejiang,
China 310007

T +86 571 876 31382
F +86 571 876 31385

AsiaPacific@purolite.com

Algeria
Australia
Bahrain
Brazil
Canada
China
Czech Republic
France
Germany
India
Indonesia
Israel
Italy
Japan
Jordan
Kazakhstan
Korea
Malaysia
Mexico
Morocco
New Zealand
Poland
Romania
Russia
Singapore
Slovak Republic
South Africa
Spain
Taiwan
Tunisia
Turkey
UK
Ukraine
USA
Uzbekistan

Purolite® Life Sciences

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

Over three 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.

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.

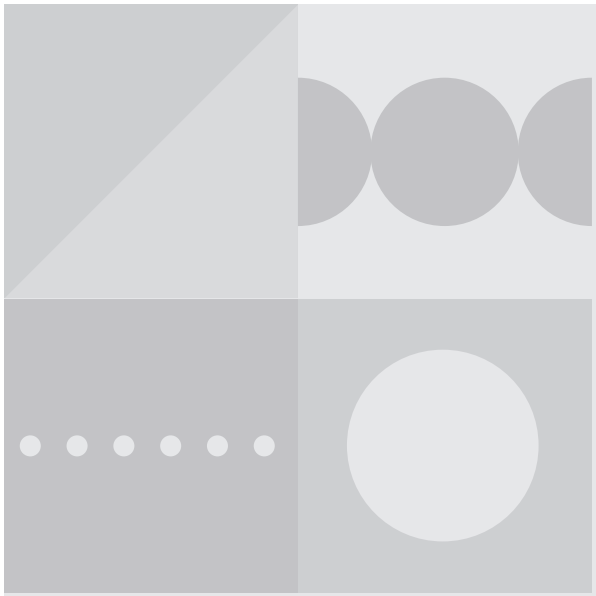
100% focused on resin technology.

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

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.



Purolite®
Life Sciences