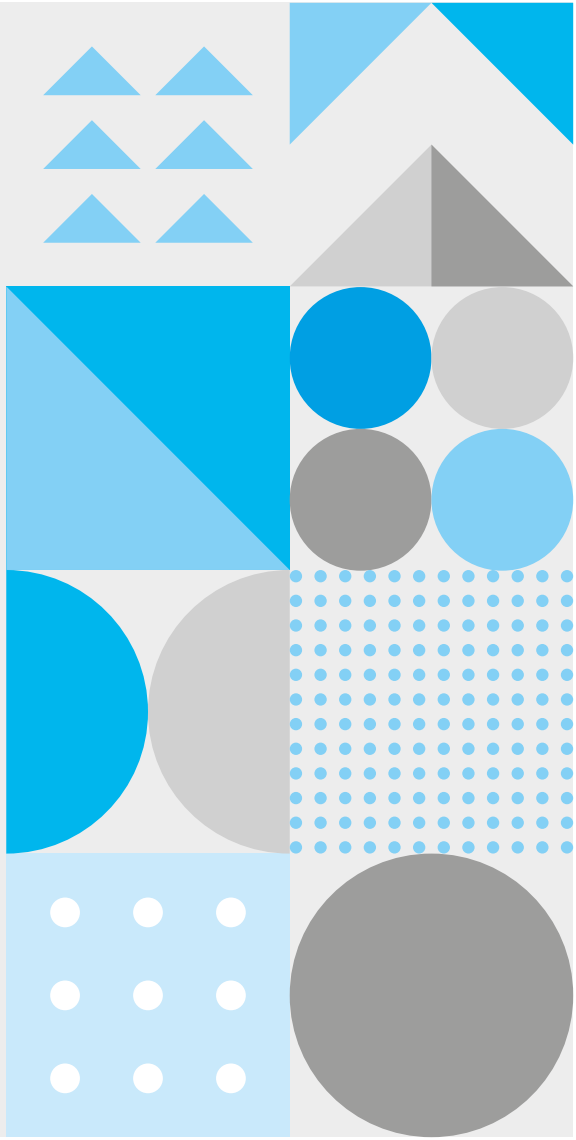
Praesto®

Jetted 35 µm

Ion Exchange Chromatography Resins



Purolite®
Life Sciences

Your solutions company

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

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.

Jetting - A patented, innovative manufacturing process for superior resin bead uniformity, performance and column packing consistency.

Introduction

Purolite® Life Sciences has revolutionized the future of Protein A chromatography with Praesto® Jetted resins. It is the only bioprocess-scale agarose resin available with uniform particle sizes for superior performance.

Manufactured with highly crosslinked agarose, Praesto SP 35 µm (cation) and Praesto Q 35 µm (anion) provide high resolution polishing resins for recombinant proteins and other biomolecules.

Key features

Uniform particle sizes

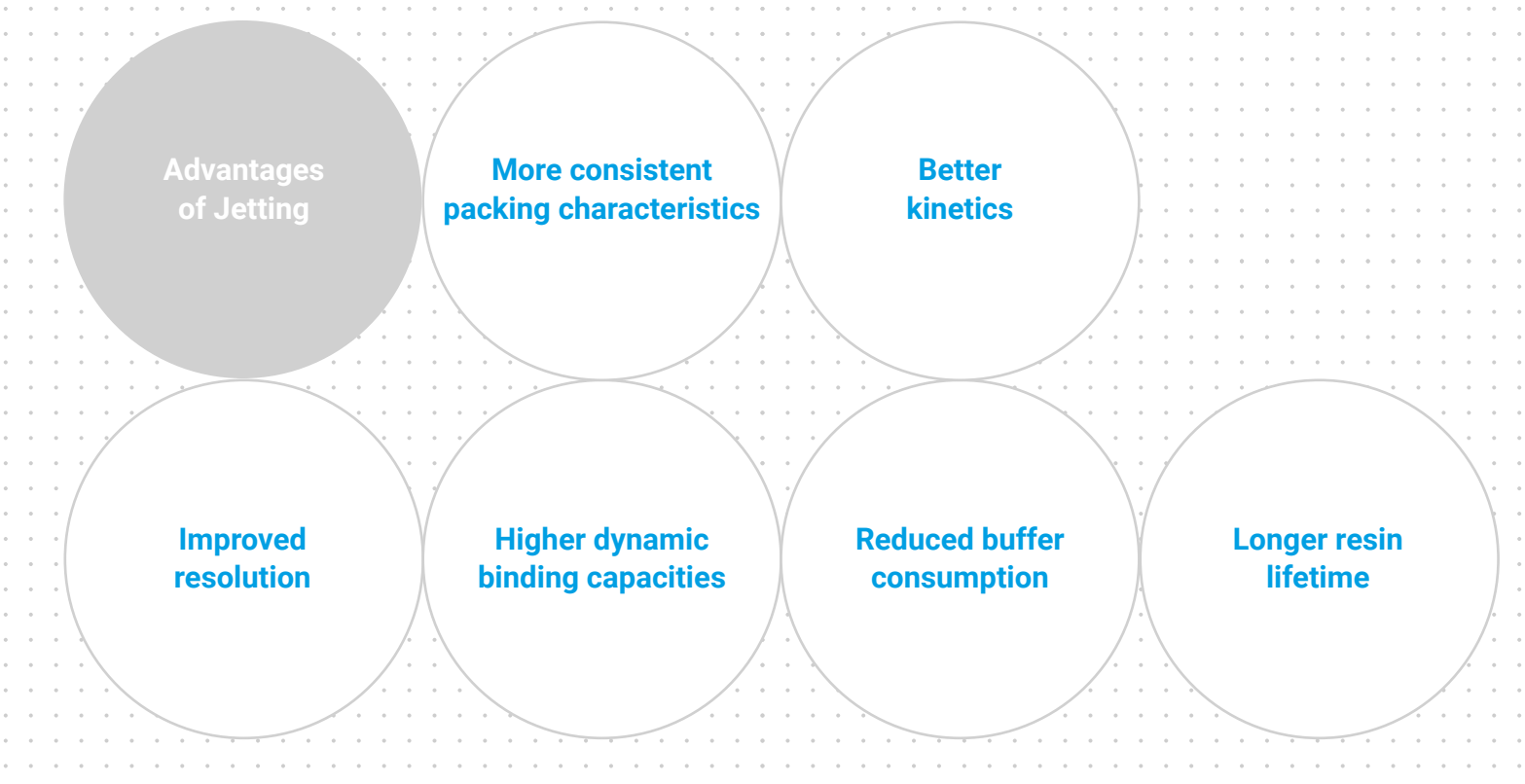
Increased dynamic binding capacity

Chemically stable

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

Non-solvent, green manufacturing

Praesto® Jetting Advantages

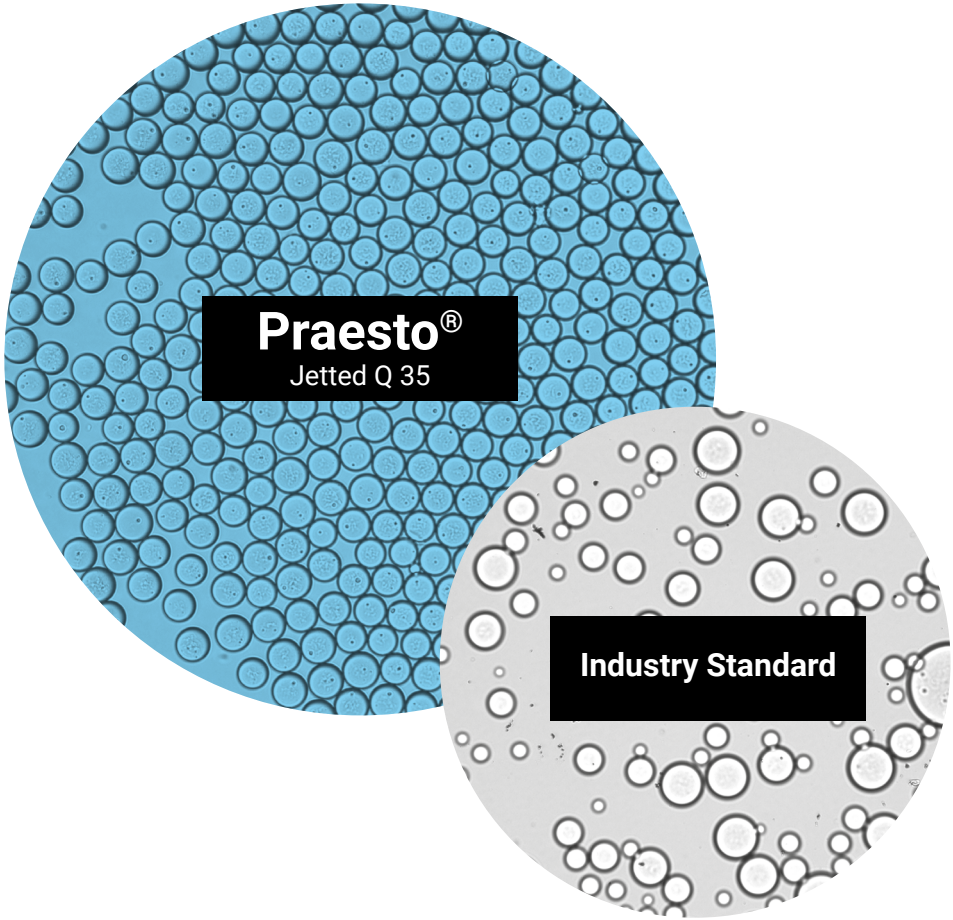


“Purolite Life Sciences is the only provider in the world capable of supplying these enhanced, uniform beads in process-scale volumes.”

Background

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

They are manufactured using ‘Jetting’ - a new, patented manufacturing 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 these uniform particle size beads.



Praesto®Jetted resins demonstrate superior performance characteristics including:

- **Increased pressure/flow properties**
- **Improved resolution from uniform particles**
- **Improved packing reproducibility and stability**
- **Higher dynamic binding capacity**
- **Green manufacturing**

Figure 1: Microscope image - Praesto® Jetted agarose resins

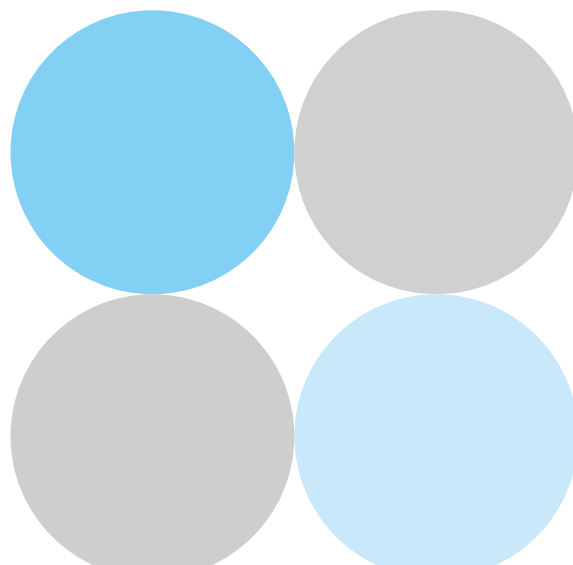

Jetting removes the need for the extensive sieving process found in traditional batch wise emulsification technology.
This generates considerably less waste and results in shorter lead times.

The Jetting Process

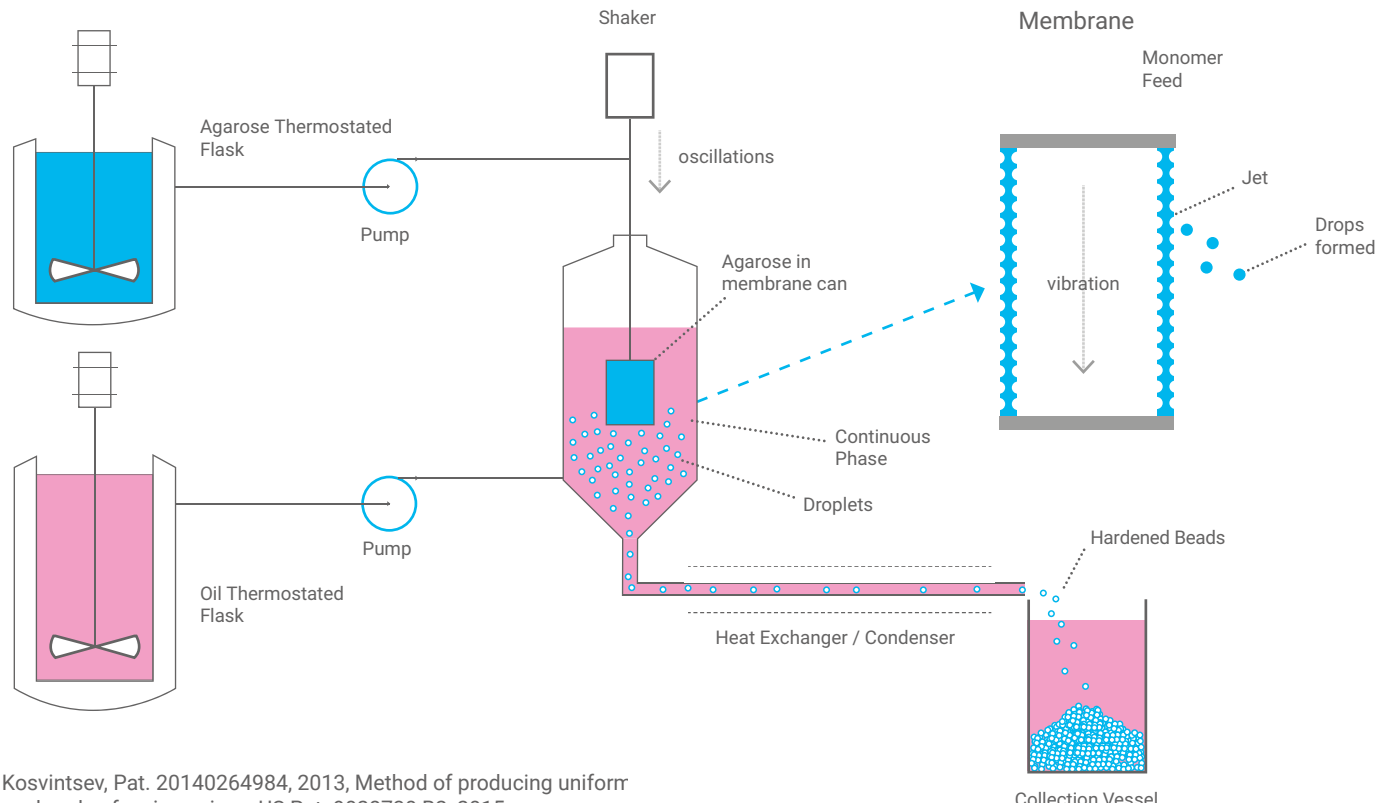
Praesto® Jetted products are manufactured using a patented, continuous technology called ‘Jetting’.

This process involves an agarose solution pumped through a specially-engineered steel membrane or can into a mineral oil, forming a suspension with a narrower particle size distribution (UC <1.3) than traditional resins (UC <1.9).

A high yield, economical process, it provides Praesto® Jetted products with unique performance characteristics.”



The Jetting Process continued...



S. R. Kosvintsev, Pat. 20140264984, 2013, Method of producing uniform polymer beads of various sizes. US Pat. 9028730 B2, 2015

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, dramatically lowering lead times and improving the overall supply chain.

Since the beads are uniform in size, it removes the need for extensive sieving, thus generating 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, like toluene commonly used in traditional manufacturing and is a major advancement in ‘green manufacturing’

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.

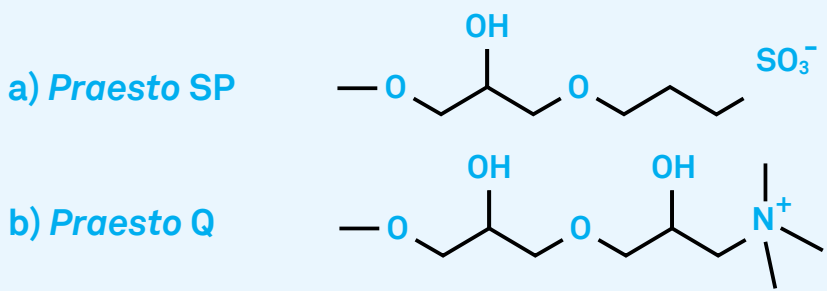


Figure 2. Ion structure or Praesto SP and Praesto Q

Praesto® Q: Typical Physical & Chemical Characteristics

Application
mAb purification

Polymer Structure
Cross-linked agarose,
uniform size beads

Appearance
Spherical, uniform size beads
supplied in 20% ethanol slurry.

Functional Group
$CH_2N^+(CH_3)_3$

Binding Capacity
> 80 mg/ml BSA at 6 mins resi-
dence time

Average Particle Size
35 µm

Ionic Capacity, mmol/mL Resin
0.14 - 0.18

pH Stability, (Long-term)
3-13

pH Stability (Short-term)
2-14

Recommended Storage
20% ethanol, 4-30°C

Flow velocity
>150

1 d50v is the median particle size of the cumulative volume distribution.

Praesto® SP: Typical Physical & Chemical Characteristics

Application
mAb purification

Polymer Structure
Cross-linked agarose, uniform size beads

Appearance
Spherical, uniform size beads supplied in 20% ethanol slurry.

Functional Group
$CH_2CH_2CH_2S03-$

Binding Capacity
> 90 mg/ml IgG at 6 mins residence time

Average Particle Size
35 µm

Ionic Capacity, mmol/mL Resin
0.11 - 0.16

pH Stability, (Long-term)
4-13

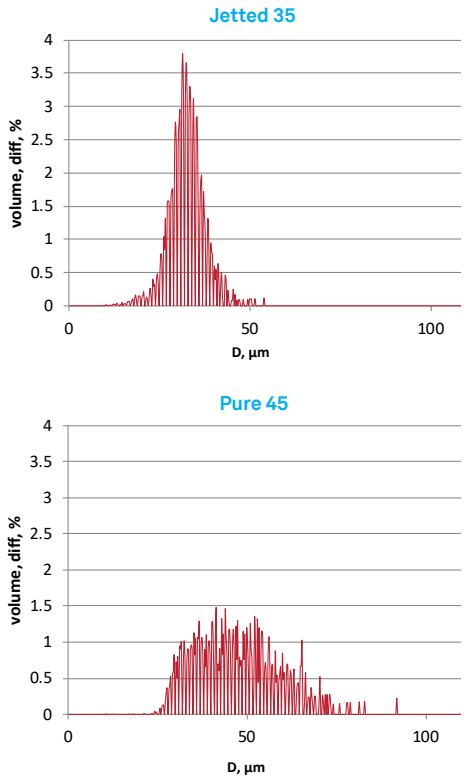
pH Stability (Short-term)
3-14

Recommended Storage
20% ethanol, 4-30°C

Flow velocity
>150

1 d50v is the median particle size of the cumulative volume distribution.

Particle Size Distribution



The particle size distribution of jetted agarose is significantly improved compared to batch emulsification.

A 35 µm jetted = 95% within 25 – 50 µm with a uniformity coefficient* of <1.3.

A 45 µm batch emulsified = 95% within 25 - 100 µm with a uniformity coefficient of 1.9.

Figure 3. Particle Size Distribution

**Uniformity coefficient (UC) is defined as the $D_{60}(V)$ divided by the $D_{10}(V)$.*

Pressure Flow

With new crosslinking methods, combined with jetting technology, Purolite Life Sciences have been able to develop 35 µm small particles for improved resolution for high polishing applications that are still suitable for large scale bioprocessing. For instance, a 45 µm batch emulsified bead has a lower pressure flow rate capability compared to a 45 µm 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 µm batch emulsified resin flow velocity reached 220 cm/h compared to the same size jetted resin (45 µm) which reached a maximum flow velocity of 282 cm/h.

D_{50}	IgG DBC (10%) 2.4 min	IgG DBC (10%) 6 min	Flow Velocity (cm/h) 20 cm bed height
Batch Emulstification	**68**	**97**	**220**
45 (Jetted)	**80**	**108**	**282**

Application Example

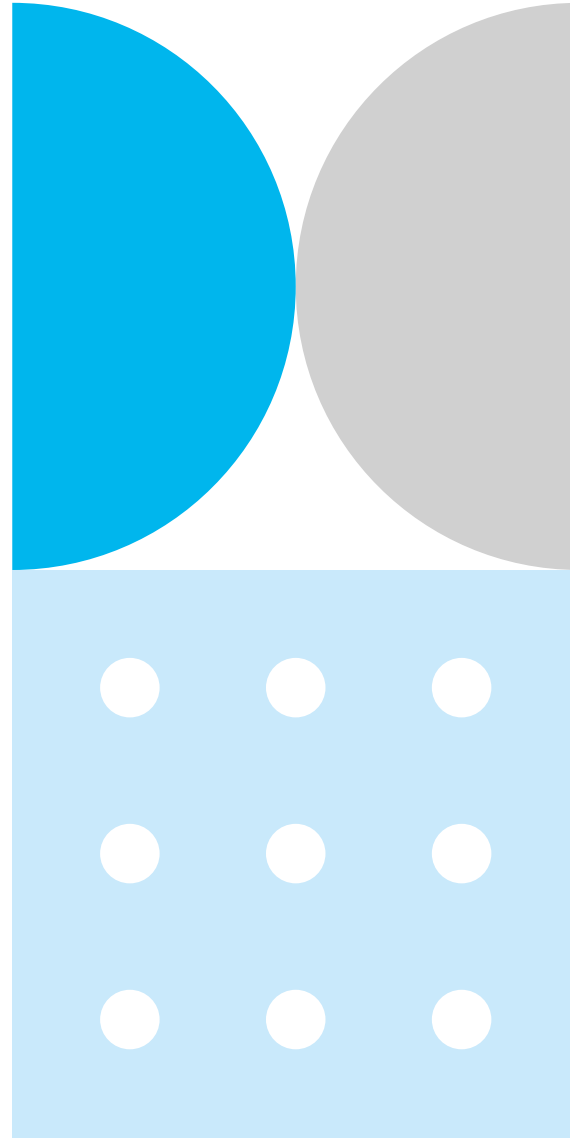
To demonstrate the high resolution of jetted agarose base beads over batch emulsified resins, we assessed the separation profiles of Praesto® cation exchangers to reduce the acidic species using a customer-supplied biosimilar MAb.

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 resins.

1) SP 45 µm - a traditional batch emulsified agarose resin (95% within 25-100 µm)

2) 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 (batch emulsified) with Jetted SP 35, a far more pronounced shoulder of the acidic species can be seen on the chromatograms.

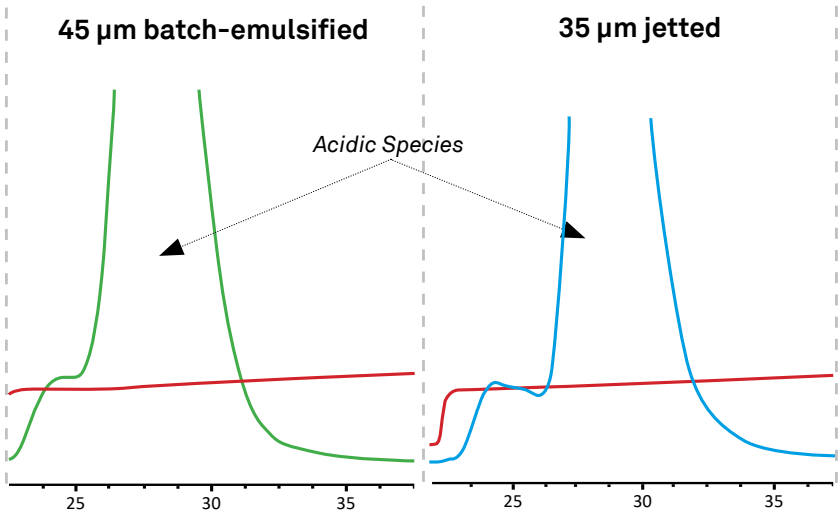


Figure 4. Comparing SP 35 and SP 45


Stability from
a robust supply
chain

Complete regulatory support

For over 35 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 pharma and food industries.

For 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

Safety data

Purolite Life Sciences maintains Material Safety Data Sheets (MSDS for the U.S. and ERSDS for Europe) on each 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 Life Sciences 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.

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. Praesto® Jetted A50 can be supplied loose in the following pack sizes; 25ml, 100ml, 500ml, 1L+ on request.

It can also be supplied pre-packed into OPUS® columns by Repligen®. Available in RoboColumns with 200 µl column volumes, and MiniChrom available in 1 and 5 ml column volumes.

For scale up/validation, pilot manufacturing and cGMP manufacturing operations we have an agreement with Repligen® to pack Praesto® resins in 0.5 cm diameter to 80 cm diameter OPUS® columns with flexible bed heights.

If you would like to discuss how Praesto® Jetted SP or Q can benefit your purification process, we have dedicated experts on-hand across the globe to provide knowledgeable, same-day technical assistance.

How to order - Jetted SP 35

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

PRODUCT	COLUMN SIZE	ORDER NUMBER
Praesto® Jetted SP35 HT	1 ml Column	PR00432-275*
Praesto® Jetted SP35 HT	5 ml Column	PR00432-276*

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

How to order - Jetted Q 35

BULK RESIN	PACK SIZE	ORDER NUMBER
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

PRODUCT	COLUMN SIZE	ORDER NUMBER
Praesto® Jetted Q35 HT	1 ml Column	PR00436-275*
Praesto® Jetted Q35 HT	5 ml Column	PR00436-276*

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

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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.

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.

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