



Affinity Chromatography Resins for Complex Antibody Purification

Affinity solutions for purifying
next-generation antibodies
capable of binding to multiple
antigens or epitopes.

ECOLAB[®]

Ecolab's Affinity Toolbox for Antibody Purification

A Revolution in Monoclonal Antibody Drug Development

Monoclonal antibodies as therapeutic agents have revolutionized medicine over the last twenty years, and many such molecules are now employed to treat a wide range of diseases. At the same time, research has continued targeting new diseases and developing further modified antibody structures with favourable properties.

Now, a second revolution is taking place with the development and commercialization of complex molecules – new antibody formats such as multispecifics, bispecifics and fragments, which pose significant purification challenges to drug developers.

**“70% of our antibody pipeline
is bispecifics and fragments”**

— Leading Pharmaceutical Company

PRAESTO™ AP+ RESIN PLATFORM

Advanced purification to improve manufacturing efficiencies.

DURA CYCLE™ A50

Designed to deliver extended resin lifetime, lowering the cost per gram.

PRAESTO™ JETTED A50

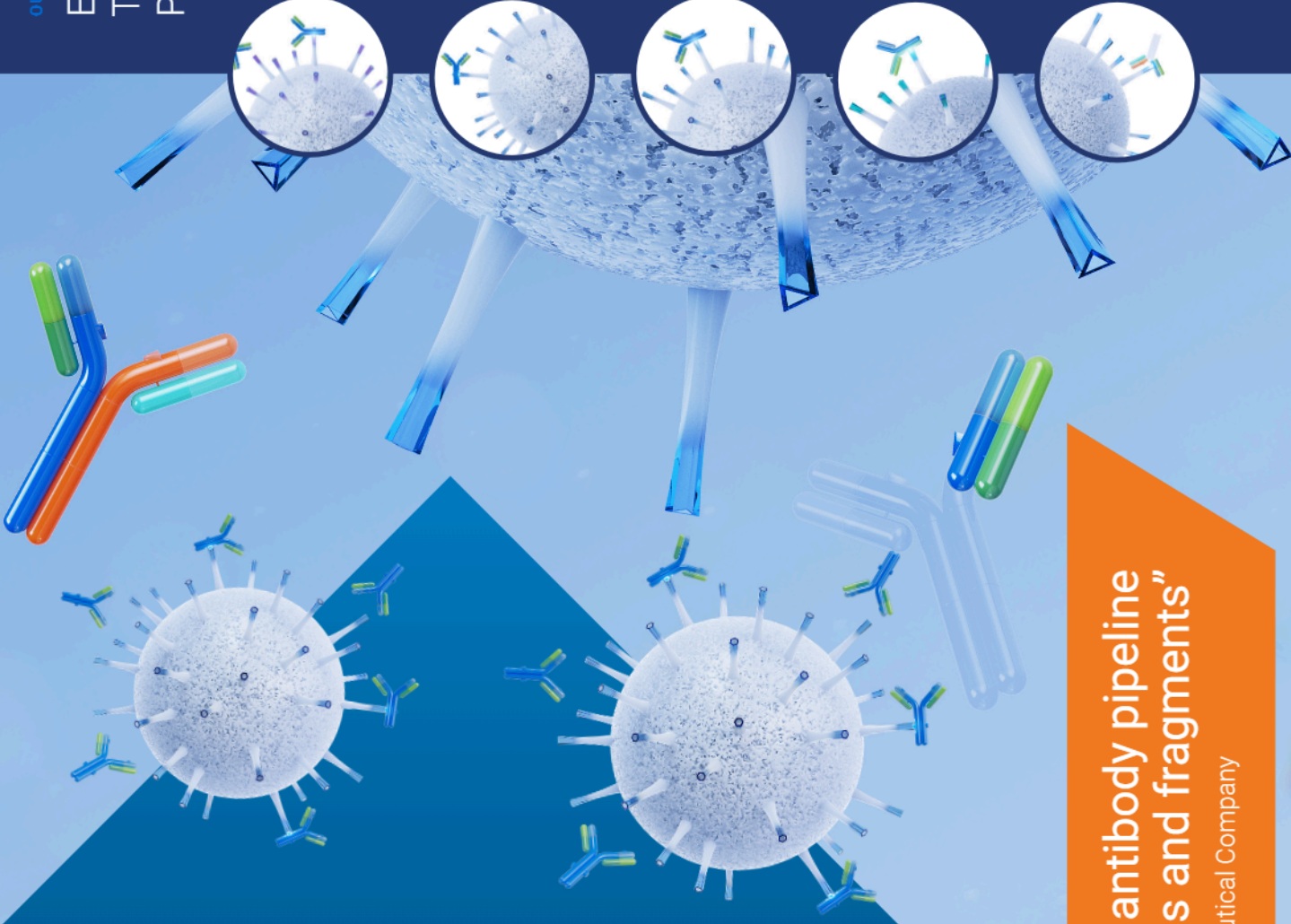
Supports process intensification, as a time-tested affinity resin.

PRAESTO™ JETTED A50 HIPH

Limits aggregation and increases purity, offering a wider pH window.

PRAESTO™ 70 CHI

Targets CH1 antibody domains, simplifying complex purifications.



Complex Molecules – The New Frontier

The transition from traditional monoclonal antibodies (mAbs) to more complex therapeutic modalities represents a significant trend in the biopharmaceutical industry. This shift is driven by multiple factors, including:

COMPLEXITY AND SPECIFICITY OF TARGETS

Many diseases involve intricate and multifactorial biological systems. Newer agents such as bispecific antibodies, antibody-drug conjugates (ADCs), and engineered proteins that target multiple pathways or cellular interactions offer improved efficacy and reduced side effects.

TECHNOLOGICAL ADVANCEMENTS

Advancements in biotechnological methods – including CRISPR gene editing, synthetic biology, and high-throughput screening – enable the design of more sophisticated therapeutic candidates.

REGULATORY AND DEVELOPMENTAL CONSIDERATIONS

As regulatory scrutiny intensifies, there is increasing emphasis on the safety, efficacy and value of new therapies in terms of patient outcomes. More complex molecules enable personalized medicine approaches, which aligns with precision in treatment development.

COMPETITIVE MARKET DYNAMICS

With the rise of biosimilars there is competitive pressure to innovate to address smaller and more complex patient populations. This has prompted the exploration of next-generation therapies that deliver differentiated and improved treatment options.

EVOLVING PATIENT EXPECTATIONS

Patients and healthcare providers prioritize treatments that enhance both survival and quality of life. More complex therapeutics, which offer targeted and personalized approaches, can provide minimized side effects, aligning treatment strategies with modern patient needs.

The Challenge of Affinity Purification of Complex Molecules

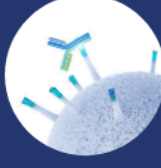
Complex molecules such as bispecifics and fragments can present unique challenges in affinity purification. Their unique and varied structures render approaches employed for standard monoclonal antibodies unsuitable or may necessitate the need for additional costly purification steps. Two such issues are the loss of bioactive material through aggregation, and the unsuitability of Fc binding to enable efficient purification.

ANTIBODY AGGREGATION



Complex molecules typically involve multiple differentiated binding sites for their efficacy. The low pH values required for elution in affinity purification can lead to aggregation, the loss of biologically active material and therefore increased production costs.

SOLUTION



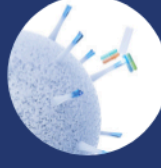
Prasesto Jetted A50 HiPh

IMPRACTICAL OR NON-EXISTENT FC BINDING



Protein A resins target binding to the Fc region. However, complex molecules may either have no Fc region, or closely associated Fc structures, so Fc binding will not effect an efficient purification.

SOLUTION



Praesto 70 CH1

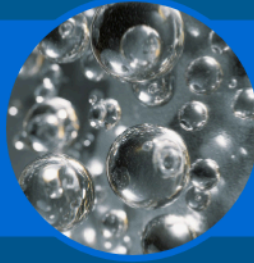
JETTING IS A **PATENTED** AND
ENHANCED MANUFACTURING
PROCESS THAT STREAMLINES
PRODUCTION STEPS

How do manufacturing
techniques differ?

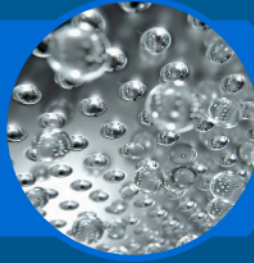
Addressing Antibody Purification – Ecolab's Purolite™ Resins

Ecolab's range of resins for the bioprocessing industry are produced by a patented jetting process resulting in uniform beads. The outcome is excellent capacity, flow and packing properties, coupled with sustainability benefits when compared to traditional emulsification techniques.

**Batch
Emulsification**
(Legacy manufacturing
technique)



**Patented Jetted
Manufacturing**



Reduced raw materials
consumption

Shorter
lead time

Increased product
consistency

Reduction in
production steps

Increased
efficiency

Reduction of
inorganic solvents

The Benefits of Jetted Resin Manufacturing

Complex Molecules in Focus

Ecolab produce a range of affinity resins for monoclonal antibody purification, with two showing specific properties that make them particularly successful in complex molecule purification:

PRAESTO JETTED A50 HIPH

A platform resin solution for acid-labile and aggregation-prone molecules. A novel protein A based affinity resin for the first stage purification of monoclonal antibodies that are pH sensitive or prone to aggregation.



Good capacity for
effective process
efficiency



Optimal flow
properties



Good caustic
stability and
cycle count



Available from
lab to process
scale

PRAESTO 70 CH1

A platform resin solution for Fabs, multispecifics and Fc-silent molecules. A novel affinity resin that selectively targets the CH1 domain of antibodies, rather than the Fc domain targeted by protein A based technologies.



High capacity for
greater process
efficiency



Optimal flow
properties



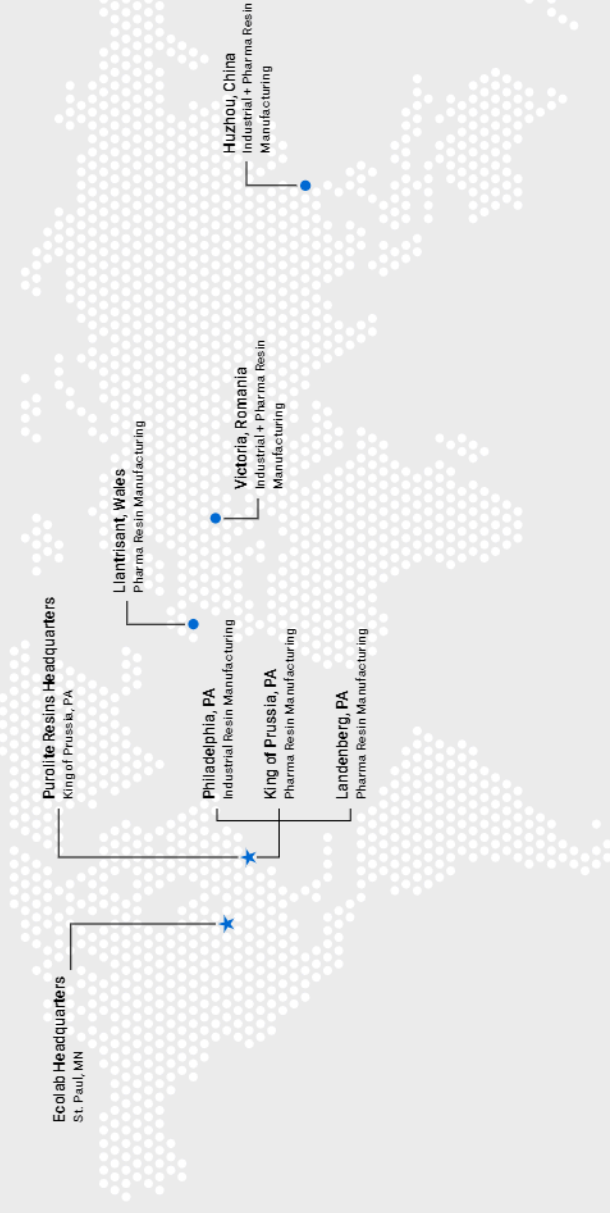
Good caustic
stability and
cycle count



Available from
lab to process
scale

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](https://www.PuroliteResins.com)



We're ready to solve your process challenges.

For further information on products and services, visit [PuroliteResins.com](https://www.PuroliteResins.com) or complete a Contact Us form via [PuroliteResins.com/contact-us](https://www.PuroliteResins.com/contact-us) or use the QR code.

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