Affinity Chromatography Resins for Complex Antibody Purification

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



ECOLAB®

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

OUR PRODUCTS

Ecolab’s Affinity Toolbox for Antibody Purification

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.

PRASESTO™ JETTED A50 HIPH

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

PRAESTO™ 70 CH1

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.

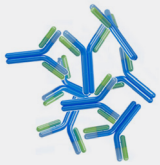
EVOLVING PATIENT EXPECTATIONS

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

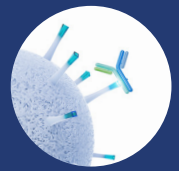
Complex molecules such as bispecifics and fragments can present unique challenges in affinity purification. Their unique and varied structures render approaches employed for standard monoclonal antibodies unsuitable or may necessitate the need for additional costly purification steps. Two such issues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

ANTIBODY AGGREGATION



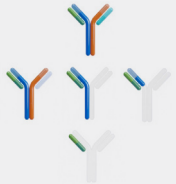
Complex molecules typically involve multiple differentiated binding sites for their efficacy. The low pH values required for elution in affinity purification can lead to aggregation, the loss of biologically-active material and therefore increased production costs.

SOLUTION



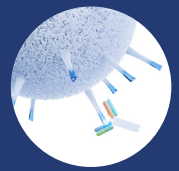
Prasesto Jetted A50 HipH

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

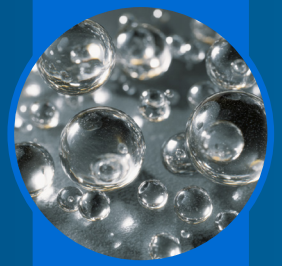
Addressing Antibody Purification — Ecolab's Purolite™ Resins

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.

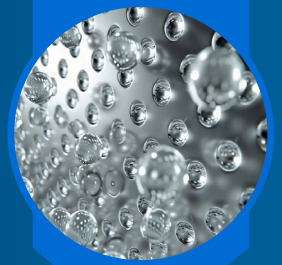
JETTING IS A PATENTED AND ENHANCED MANUFACTURING PROCESS THAT STREAMLINES PRODUCTION STEPS

How do manufacturing techniques differ?

Batch Emulsification
(Legacy manufacturing technique)



Patented Jetted Manufacturing



The Benefits of Jetted Resin Manufacturing

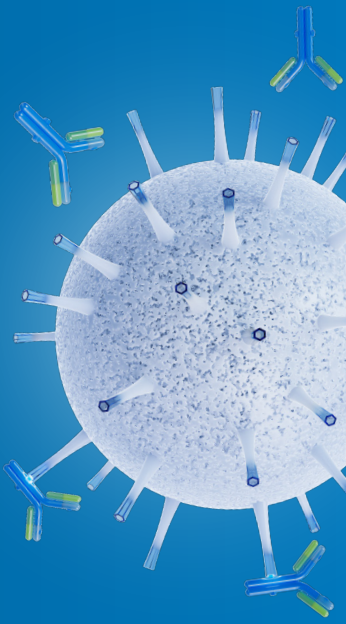
- Reduced raw materials consumption
- Shorter lead time
- Increased product consistency
- Reduction in production steps
- Increased efficiency
- Reduction of inorganic solvents

Complex Molecules in Focus

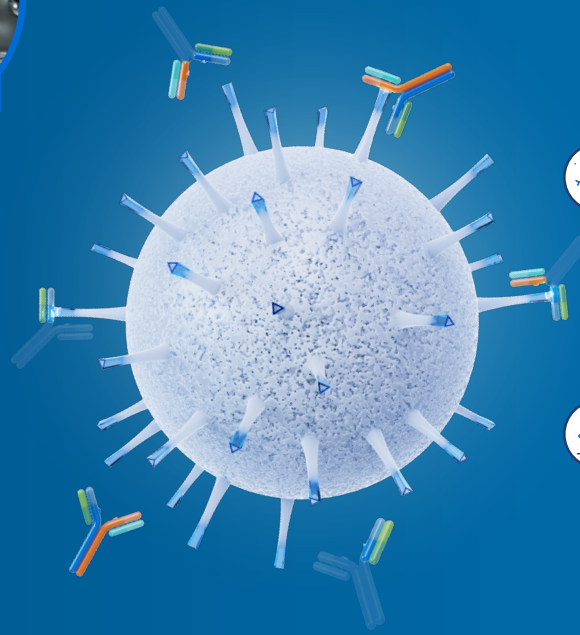
Ecolab produce a range of affinity resins for monoclonal antibody purification, with two showing specific properties that make them particularly successful in complex molecule purification:

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



- High capacity for greater 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.

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



We're ready to solve your process challenges.

For further information on products and services, visit PuroliteResins.com or complete a Contact Us form via PuroliteResins.com/contact-us or use the QR code.

Contact Us Form:

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