Praesto™ Jetted A50 HipH

A novel protein A resin designed specifically for elution of Fc-containing molecules at higher pH levels

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Introduction

For large-scale purification of antibodies and Fc-fusion proteins, protein A affinity chromatography is used in the capture step for almost every established purification platform. Combining high purity and yield, with concentration and rapid transfer into a stable intermediate makes protein A affinity chromatography ideal. Today, all protein A resins on the market require acidic conditions of pH 3 - 4, to achieve a quantitative elution into a reasonable pool volume (2 - 3 column volumes).

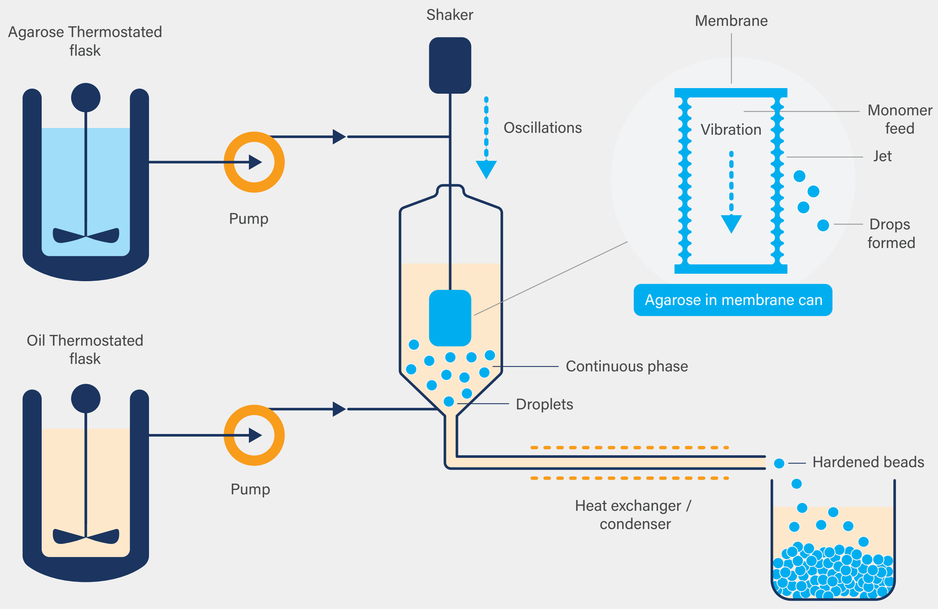
However, with the advancement of antibody engineering and drug development, new antibody types such as Fc-fusion proteins and other antibody-derived drugs are emerging. This type of molecule is commonly more sensitive to acidic conditions and will in some cases aggregate when typical protein A elution buffers are used.

In this poster we present application data from the use of a new protein A resin, Praesto Jetted A50 HipH, which enables elution of Fc-containing molecules up to pH 5.0.

Key Features

- Mild elution – up to pH 5.0.
- Up to 60 mg/ml dynamic binding capacity for polyclonal human igG.
- Uniform jetted beads – efficient mass transfer.
- Resistant to 0.1 M NaOH for >100 cycles (15 min contact time).

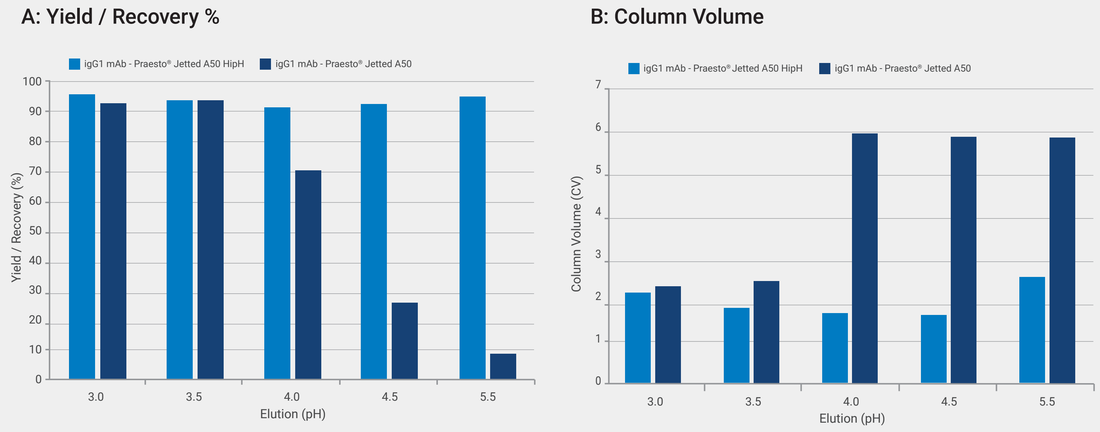
Fig 1. Jetting Technology



To streamline development of this novel resin, an established base matrix, already used in commercial manufacturing was chosen. The base matrix is a 50 µm agarose bead produced with a proprietary manufacturing method from Ecolab for Purolite Resins, called Jetting technology.

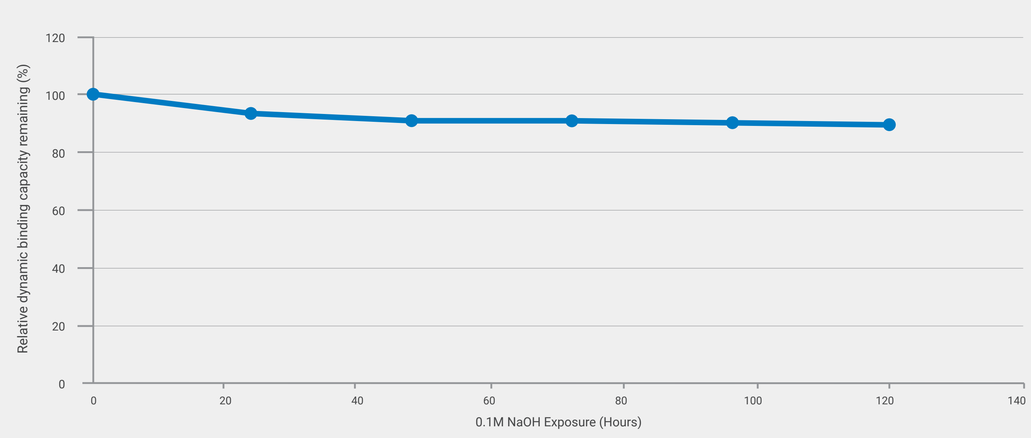
Jetting technology is a continuous emulsification process that generates agarose beads with a narrow particle size distribution. Jetting was purpose-designed to improve security of supply and reduce environmental impact in agarose resin manufacture.

Fig 2. Innovative High pH Elution Technology



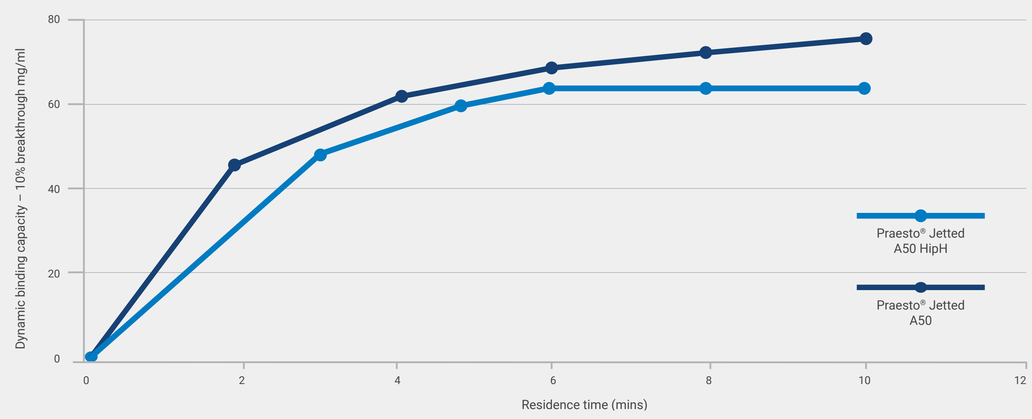
The unique ligand design allows for elution at a wider range of pH (3 - 5) when compared to commercially-available alternatives without impacting yield, purity or elution volumes (Fig 2).

Fig 3. Alkaline Stability



Sodium hydroxide (NaOH) exhibits high efficiency in removing bound proteins, nucleic acids, and lipids from bioprocess resins, alleviating the risk of fouling on heavily burdened protein A columns. Praesto Jetted A50 HipH maintains excellent capacity after exposure to 0.1 M NaOH for 120 hours, facilitating efficient CIP and longer resin lifetime (Fig 3).

Fig 4. Dynamic Binding Capacity



The uniform jetted bead maintains high mass transfer and high capacity even at low residence times. Praesto Jetted A50 HipH shows comparable performance for polyclonal IgG capacity to Praesto Jetted A50 (Fig 4).

Summary

- A new protein A resin for pH-sensitive, Fc-containing proteins has been developed
- Elution is possible up to pH 5 with standard buffers
- Based on an established uniform agarose bead, already used in FDA-approved commercial manufacturing processes – same as Praesto™ Jetted A50