

GeloPure Butyl

Hydrophobic Chromatography Media

Technical Datasheet

Aggregates removal

GeloPure Butyl resin is a chromatography media, can remove aggregates efficiently from antibodies, synthesized by standard polysaccharide ligand modification technology. After affinity chromatography like protein A, protein L or protein G, the antibody samples are passed through GeloPure Butyl chromatography, the aggregates are bound to the hydrophobic ligand of the chromatography media and antibody monomers are coming out in flowthrough fraction. GeloPure Butyl can be used as flow-through purification mode that selectively binds such as aggregates or polymers.

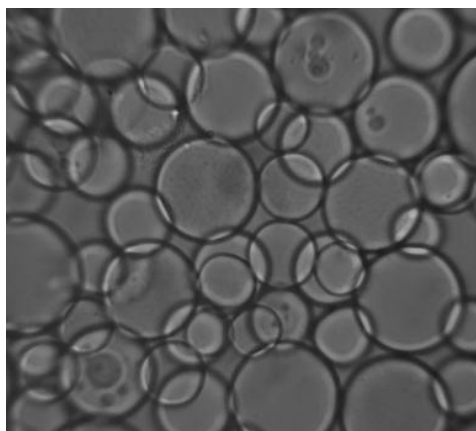
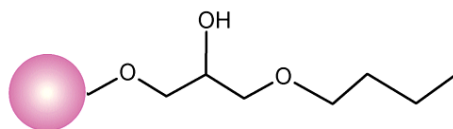


Fig 1. OPM analysis of GeloPure Butyl resin

GeloPure Butyl base resin

Cross-linked spherical GeloPure beads are prepared by unique process from natural polysaccharides. Primarily composed of agarobiose repeating units (alternating D-galactose and 3,6-anhydro-L-galactose), finally beads are highly hydrophilic, minimize the non-specific binding. GeloPure Butyl, made from cross-linked GeloPure beads, benefits from this structure by offering efficient flow velocity for large biomolecules. This helps improve performance when purifying large proteins and other biological substances.



Partial structure of GeloPure Butyl

Ligand structure for GeloPure Butyl media is described.

Characteristics		
Ligand	Butyl group	
Type	Hydrophobic	
Base Matrix	Cross-linked agarose Beads	
Particle Size (µm)	40 -130 µm (Avg: 90µm)	
pH Working Range	2 to 14	
Operating Pressure	Up to 2 bar (0.2 Mpa)	
Chemical Stability	0.5N NaOH	
Dynamic binding capacity (mg/mL resin)	HSA*	30
	Human IgG**	10
Supplied	Suspension in 20% Ethanol	

*Buffer A: 20mM sodium phosphate, 2M Ammonium sulfate: pH: 7.2

Buffer B: 20mM sodium phosphate, 0.1M Sodium chloride, pH: 6.8

**Buffer A: 20mM sodium phosphate, 1M Ammonium sulfate: pH: 7.2

Buffer B: 20mM sodium phosphate, 0.1M Sodium chloride, pH: 6.8

Characteristics of GeloPure Butyl

The basic characteristics of GeloPure Butyl resin are shown in table. GeloPure Butyl resin is based on 90 µm (average) highly cross-linked agarose beads. GeloPure Butyl resin is designed for use in bio-pharmaceuticals manufacturing processes. multiple types of hydrophobic chromatography resins we are making.

Pressure-flow Properties of GeloPure Butyl

GeloPure Butyl enable high-flow operations, for efficient purification in biopharmaceutical industries high flow operation is essential. The figures below show pressure-flow velocity curves of GeloPure Butyl. GeloPure Butyl resin is operable at practical flow velocities and pressures.

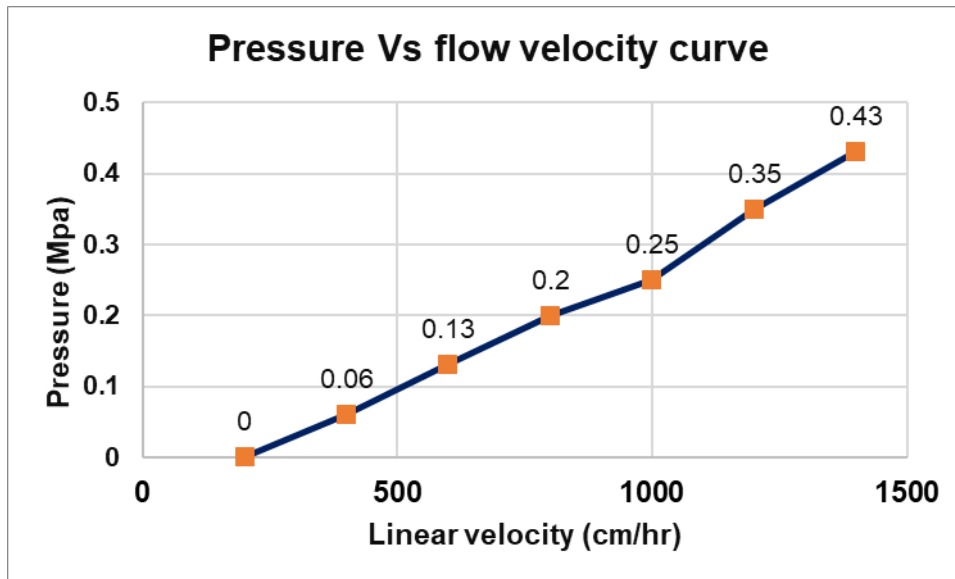


Fig.3 Pressure-flow property of GeloPure Butyl

Column: I.D.2.6 cm x H 19.3cm

Mobile phase: Pure water, 23 - 25 °C

Resin was packed with a compression factor 1.35. S

ystem pressure was excluded from the data.

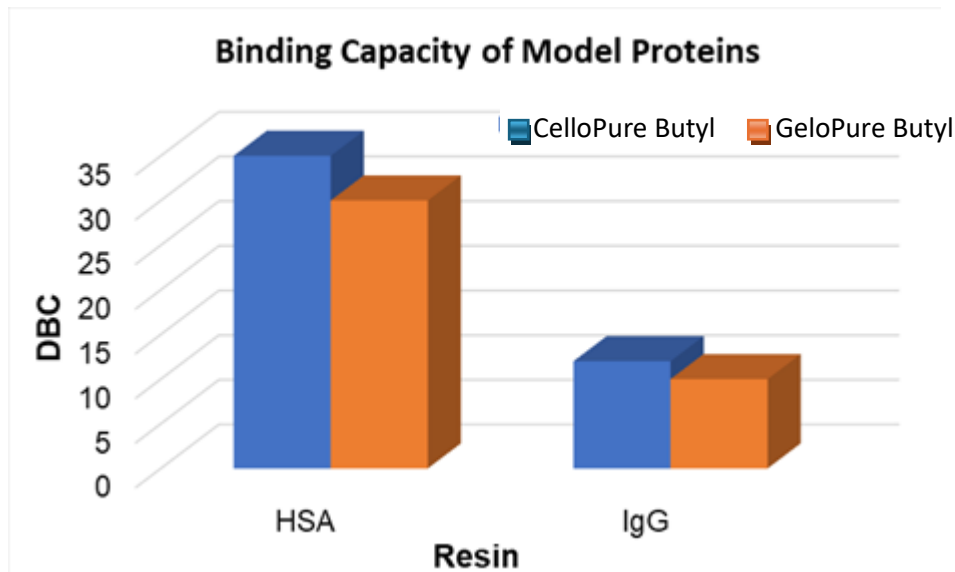
Dynamic Binding Capacities of GeloPure Butyl

GeloPure Butyl have high efficiency in mass transfer and excellent Dynamic Binding Capacities, particularly for large biomolecules like Immunoglobulins (IgG) also for HSA and Ribonuclease.

Because of these special qualities, GeloPure Butyl media can be used in downstream processes in the purification of biopharmaceuticals.

Model Protein Separation Performance

The optimum amount of ligand for HIC resins vary depending on the application. Protein separation studies show that relative binding strength are CelloPure Butyl >GeloPure Butyl. Fig. Model Proteins Separation Column: I.D. 16 mm × H 50 mm Buffer A: 20 mM Phosphate buffer, pH 7, 2 M Ammonium sulphate Buffer B: 20 mM Phosphate buffer sodium chloride, pH 7 Proteins: Albumin.



Purification of antibody aggregates

GeloPure Butyl is the best chromatography resin for removing aggregates from monoclonal antibodies in flow-through mode. Antibody aggregates were removed using the monoclonal antibody purified with a protein A or protein L columns, GeloPure Butyl can be worked with low electrical conductivity and has high agglomerate removal properties. In this study, the conductivity of the sample was adjusted to 14 mS / cm.

Column: 1 mL Mini-Column Flow rate: Residence time 4 min (75 cm/h)

Sample: Purified mAb with Protein A resin 6.6 mg/mL,
pH6, 14 mS/cm

Antibody load: 93 mg mAb/ mL_cv

Equilibration/ wash: 20 mM AcOH-Tris + NaCl, pH6,

Resin	Aggregate % (Before load)	Aggregate % (After load)	Recovery [%]
GeloPure Butyl	2.6	0.19	94

Repeat use GeloPure Butyl can be used repeatedly.

For cleaning-in-place, use a cleaning solution containing 0.5 M sodium hydroxide and 30% isopropanol. By performing cleaning-in-place with an appropriate cleaning solution, the adsorption performance did not change even after repeated use 60 times.