CelloPure Butyl

Hydrophobic Chromatography Media

Technical Datasheet

2464 Norwood street SW,
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Aggregates removal

CelloPure 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 CelloPure Butyl chromatography, the aggregates are bound to the hydrophobic ligand of the chromatography media and antibody monomers are coming out in flowthrough fraction. CelloPure Butyl can be used as flow-through purification mode that selectively bounds such as aggregates or polymers.

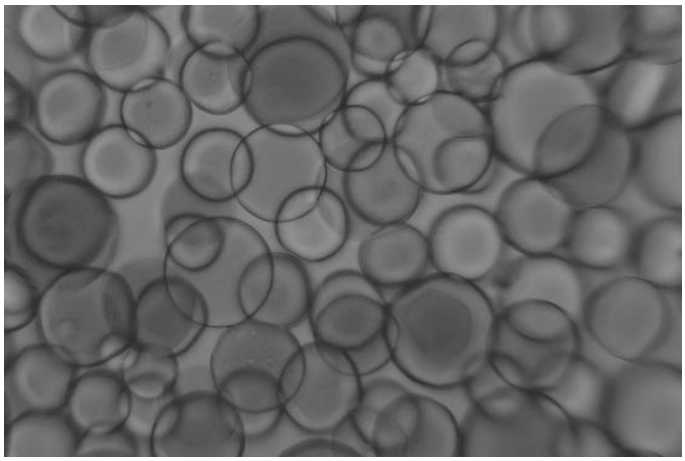
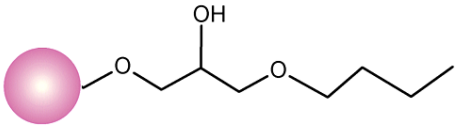


Fig 1. OPM analysis of CelloPure Butylresin

CelloPure Butyl base resin

Cross-linked spherical Cellulose beads are prepared by unique process from crystalline natural polysaccharides, differing the physical characteristics from non-crystalline polysaccharides such as agarose. Thus, CelloPure resins are highly porous in nature. Due to that porous nature of the highly crosslinked spherical cellulose bead, resins have unique mechanical strength.



Partial structure of CelloPure Butyl

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Characteristics of CelloPure Butyl

The basic characteristics of CelloPure Butyl resin are shown in table 1. CelloPure Butyl resin is based on 90 µm (average) highly cross-linked cellulose beads. CelloPure Butyl resin is designed for use in bio-pharmaceuticals manufacturing processes. multiple types of hydrophobic chromatography resins we are making.

Characteristics		
Ligand		Butyl group
Type		Hydrophobic
Base Matrix		Highly Cross-linked Cellulose Beads
Particle Size		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*	35
	Human IgG**	12
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

Pressure-flow Properties of CelloPure Butyl

CelloPure 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 CelloPure Butyl. CelloPure Butyl resin is operable at practical flow velocities and pressures.

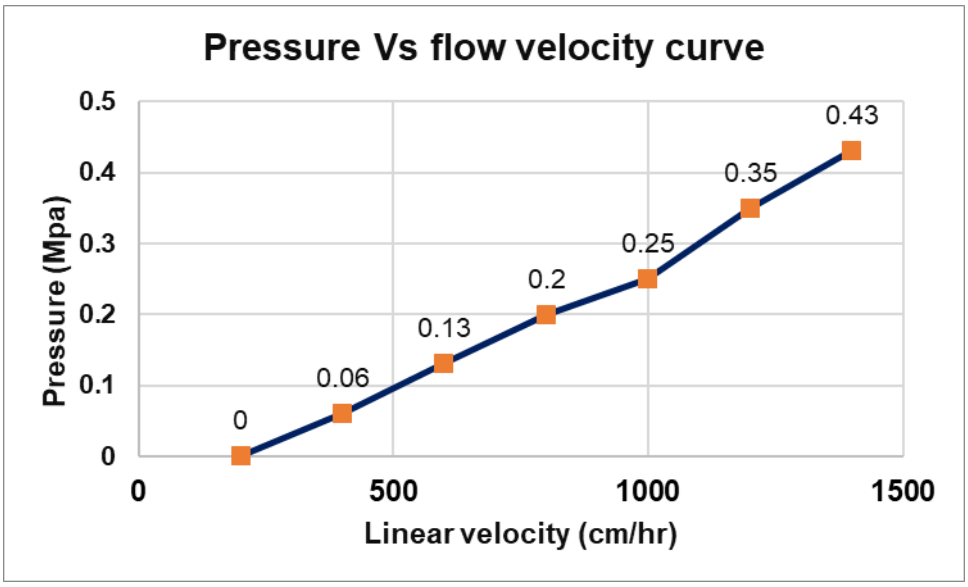


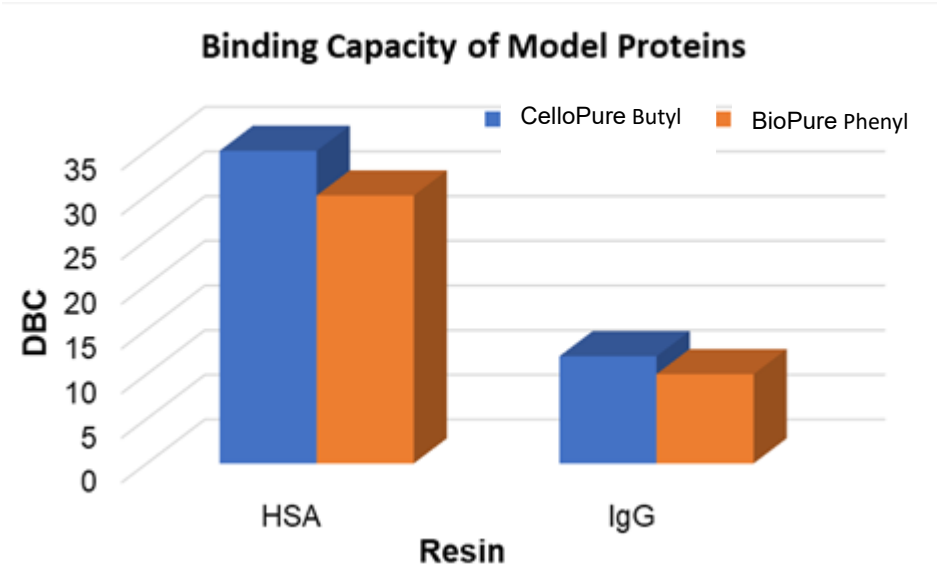
Fig. Pressure-flow property of CelloPure Butyl

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

Mobile phase: Pure water, 23 - 25 ℃

Resin was packed with a compression factor 1.1.

System pressure was excluded from the data.



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Dynamic Binding Capacities of CelloPure Butyl

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

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

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

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

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

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

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 >BioPure Butyl. Fig.4 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

CelloPure 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, CelloPure 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,

pH 6, 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 [%]
CelloPure Butyl	1.8	0.07	94

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Repeat use CelloPure 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.

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