

GeloPure Phenyl

Hydrophobic Chromatography Media

Technical Datasheet

Aggregates removal

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

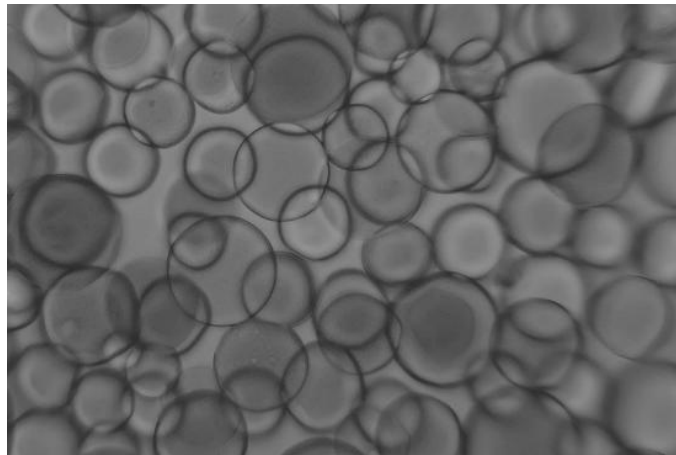
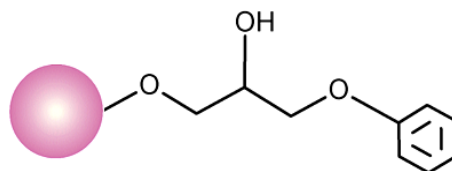


Fig 1. OPM analysis of GeloPure Phenyl resin

GeloPure Phenyl base resin

Cross-linked spherical agarose 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 Phenyl, made from cross-linked agarose 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 Phenyl

Ligand structure for GeloPure Phenyl media is described.

Characteristics of GeloPure Phenyl

The basic characteristics of GeloPure Phenyl resin are shown in table 1. GeloPure Phenyl resin is based on 4% cross-linked spherical agarose beads. GeloPure Phenyl resin is designed for use in bio-pharmaceuticals manufacturing processes. multiple types of hydrophobic chromatography resins we are making.

Characteristics		
Ligand	Phenyl group	
Type	Hydrophobic	
Base Matrix	Cross-linked Agarose Beads 4%	
Particle Size	40 µm to 165 µm	
pH Working Range	2 to 14	
Operating Pressure	Up to 2 Bar (0.2 Mpa)	
Chemical Stability	0.5N NaOH	
Binding Capacity (mg/mL resin)	HNA*	38
	Human-IgG**	15
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 GeloPure Phenyl

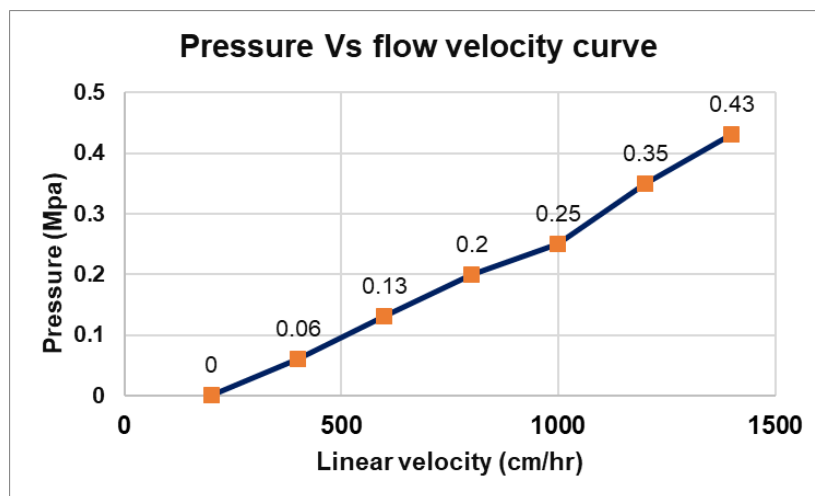
GeloPure Phenyl enable high-flow operations, for efficient purification in biopharmaceutical industries high flow operation is essential. The figures below show pressure-flow velocity curves of GeloPure Phenyl. GeloPure Phenyl is operable at practical flow velocities and pressures.

Pressure-flow property of GeloPure Phenyl

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. System pressure was excluded from the data.



Purification of antibody aggregates

GeloPure Phenyl 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 Phenyl 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 [%]
BioTrap Phenyl	2.6	0.07	90

Dynamic Binding Capacities of GeloPure Phenyl

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

Repeat use GeloPure Phenyl 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.