



Sepax Technologies

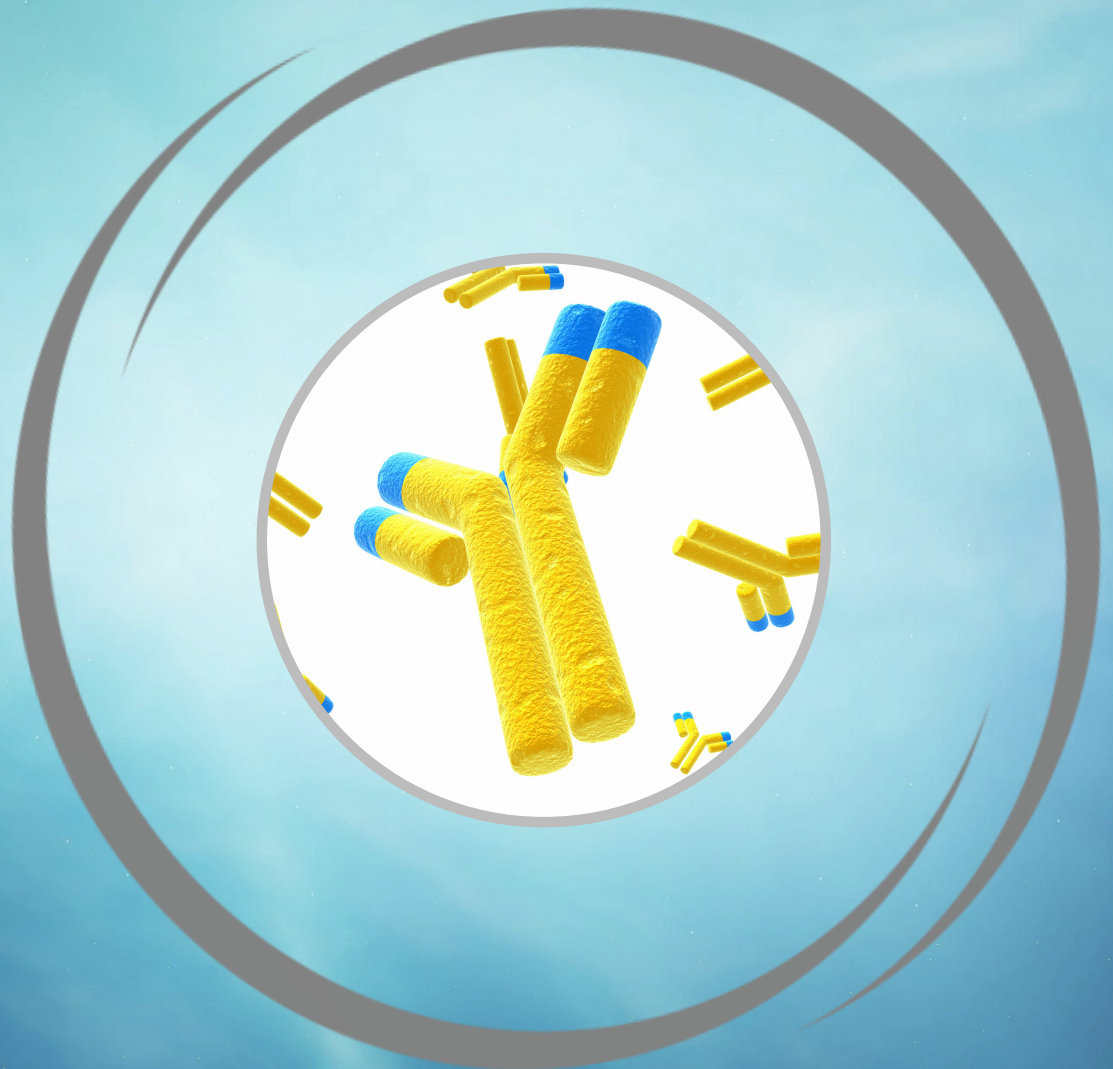
MabPurix Protein A Affinity Resins

MabPurix A Series

Agarose-based Protein A Affinity Chromatography Resins

MabPurix P Series

Polymer-based Protein A Affinity Chromatography Resins



Sepax MabPurix Resins

Introduction

MabPurix A Series: Agarose-based Protein A Affinity Chromatography Resins

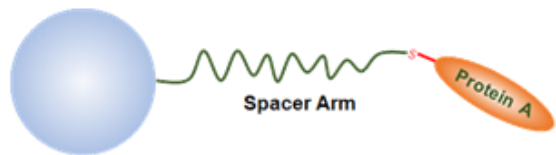
MabPurix A45 and MabPurix A65 affinity resins are based on spherical, highly cross-linked agarose beads with a narrow size distribution and high mechanical stability. The agarose base beads are covalently bonded with a base resistant recombinant Protein A through a proprietary method. MabPurix A affinity resins are specifically designed for purification applications of monoclonal antibodies and recombinant protein biomolecules containing Fc domains. Compared to other conventional agarose affinity resins, MabPurix A resins offer a better pressure resistance.

MabPurix P Series: Polymer-based Protein A Affinity Chromatography Resins

MabPurix P30 and MabPurix P45 affinity resins are made from monodispersed porous polymethacrylate based beads with average particle sizes of 30 µm and 45 µm respectively. The base beads are first treated with proprietary coating technology to provide hydrophilicity and bioinertness to avoid non-specific binding, and then are covalently bonded with a base resistant recombinant Protein A through a proprietary method. MabPurix P affinity resins are specifically designed for purification applications of monoclonal antibodies and recombinant protein biomolecules containing Fc domains.

Features

- High binding capacity
- High base resistance (0.5 M NaOH)
- Hydrophilic, biocompatible, negligible non-specific binding
- Small volume change under standard packing condition
- High pressure resistance
- Product supply capability: >100 L



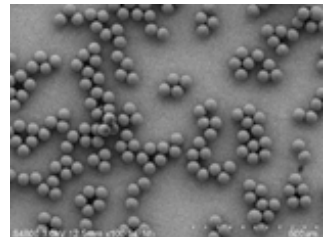
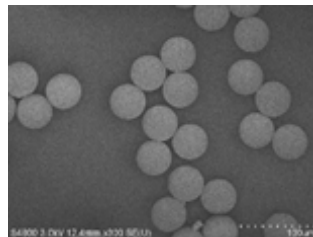
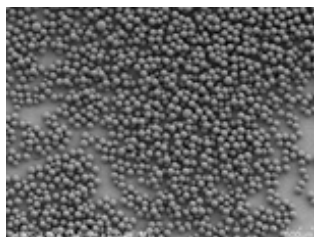
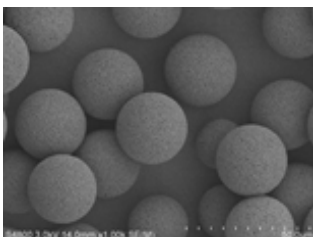
MabPurix Affinity Resin Structure

Resin Technical Specifications

Resin	MabPurix A45	MabPurix A65	MabPurix P30	MabPurix P45
Matrix	Agarose		Polymethacrylate	
Average Particle Size	45 µm	65 µm	30 µm	45 µm
Ligand	Base resistant recombinant Protein A			
DBC ¹	>70 mg hIgG/mL	>53 mg hIgG/mL	>50 mg hIgG/mL	>50 mg hIgG/mL
Max Pressure Drop	0.3 Mpa		1 MPa	
pH range	3-12		1-13	
Base resistance ²	0.5 M NaOH			
CIP	0.5 M NaOH			

DBC Test: Sample: 2.0 mg/mL Human IgG in 20 mM Sodium Phosphate + 150 mM NaCl, pH 7.4; Column: 6.6 mm x 30 mm; Residence Time: 5 min, 10% breakthrough; **Base Resistance Test:** base contact 25 h, A Series: DBC > 70% and P Series: DBC > 80%

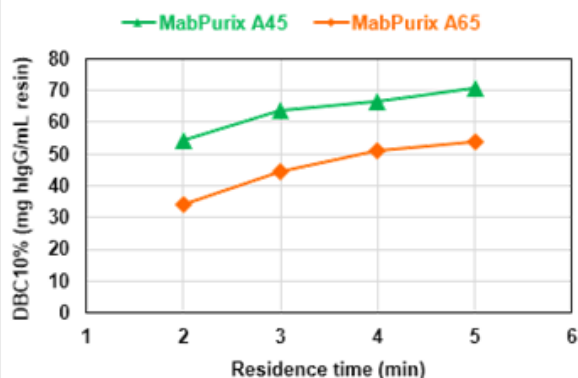
MabPurix Resin SEM Images



SEPAX MABPURIX A SERIES

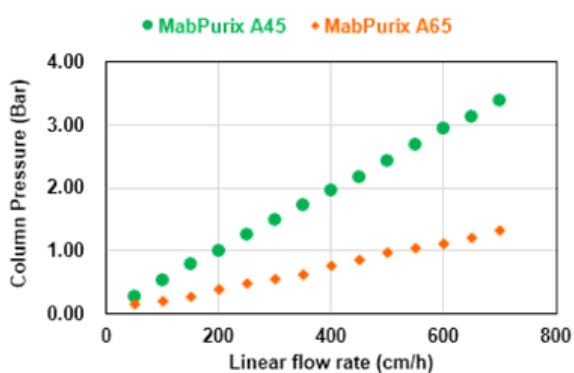
Agarose-based Protein A Affinity Chromatography Resins

MabPurix A45 and A65 Affinity Resin DBC and Residence Time



Column: Generik 6.6 mm x 30 mm UV; **Detector:** 280 nm; **Sample:** 2.0 mg/mL Human IgG in 20 mM Na-phosphate, 150 mM NaCl, pH 7.4 buffer; **Equilibrium Buffer:** 20 mM Na-phosphate, 150 mM NaCl, pH 7.4; **Elution Buffer:** 100 mM Gly-HCl, pH 3.0; **Flow Rate:** 0.513 mL/min (2 min), 0.342 mL/min (3 min), 0.257 mL/min (4 min), 0.205 mL/min (5 min)

MabPurix A45 and A65 Net Back Pressure vs. Flow-rate Curve

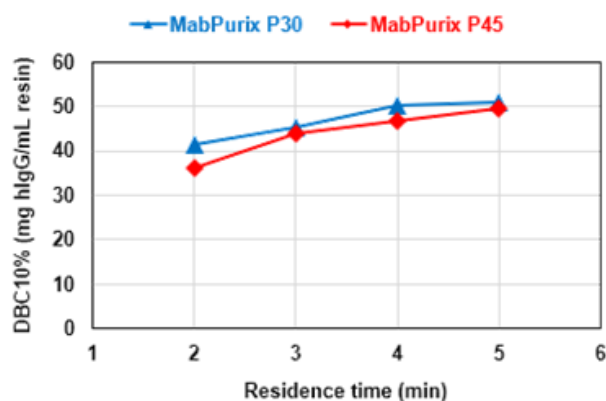


Column: Generik 6.6 mm x 20 cm; **Mobile Phase:** 20 mM Na-phosphate, 150 mM NaCl, pH 7.4

SEPAX MABPURIX P SERIES

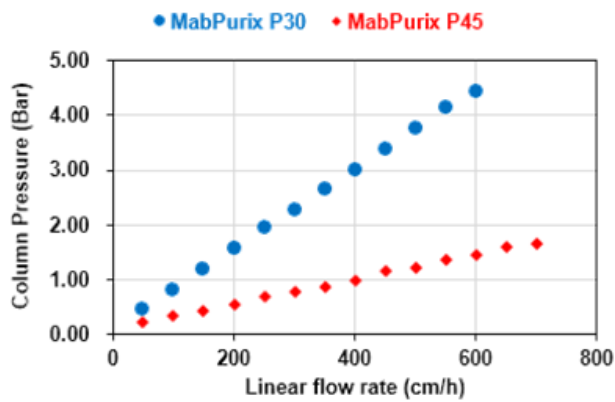
Polymer-based Protein A Affinity Chromatography Resins

MabPurix P30 and P45 DBC and Residence Time



Column: Generik 6.6 mm x 30 mm; **UV Detector:** 280 nm; **Sample:** 2.0 mg/mL Human IgG in 20 mM Na-phosphate, 150 mM NaCl, pH 7.4 buffer; **Equilibrium Buffer:** 20 mM Na-phosphate, 150 mM NaCl, pH 7.4; **Elution Buffer:** 100 mM Gly-HCl, pH 3.0; **Flow Rate:** 0.513 mL/min (2 min), 0.342 mL/min (3 min), 0.257 mL/min (4 min), 0.205 mL/min (5 min)

MabPurix P30 and P45 Net Back Pressure vs. Flow-rate Curve



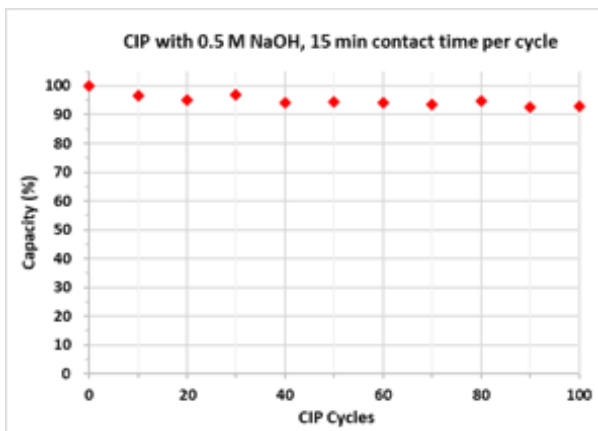
Column: Generik 6.6 mm x 20 cm; **Mobile Phase:** 20 mM Na-phosphate, 150 mM NaCl, pH 7.4

(1) Monodispersed size distribution: Particles sizes are 30 μm and 45 μm , which are monodispersely distributed, $D90/D10 < 1.3$. Also highly cross-linked resins, smooth surface, and spherical shape. Uniform particle size leads to stable column bed and save column packing time.

(2) Enable faster protein mass transfer: The dependence of DBC on residence time is small within 1.5-6.0 min residence time range, MabPurix P affinity resins reduce downstream purification time of biologics, increase production throughput using the same Mab column dimensions and the same resin bed volume.

(3) Enable faster flow rate and cut down downstream purification time: Compared to conventional agarose beads, polymethacrylate base beads have improved pressure resistance, enabling higher production throughput by using a higher flow rate (or by packing a longer column and processing more biologics per batch). For some metastable biologics which request fast purification, MabPurix P affinity resins can not only increase production throughput but also improve product yield and product quality.

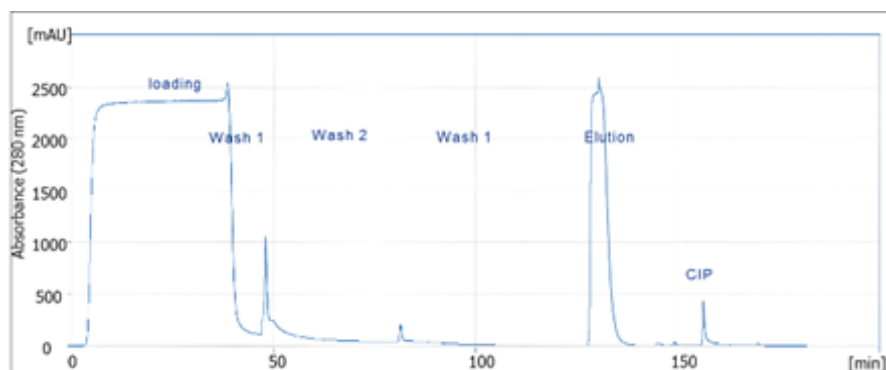
MabPurix P30 Base Resistance Test



(0.5 M NaOH CIP cycle test)

Column: Generik 6.6 mm x 30 mm; **Flow Rate:** 0.5 mL/min, DBC test at beginning and after every 10 times 0.5M NaOH CIP (10% breakthrough); **Sample:** 2.0 mg/mL Human IgG in 20 mM Na-phosphate, 150 mM NaCl, pH 7.4 buffer; **Equilibrium Buffer:** 20 mM Na-phosphate, 150 mM NaCl, pH 7.4; **Elution Buffer:** 0.1 M Na-citrate, pH 3.0; **Flow Rate:** 0.257 mL/min (4 min residence time); **CIP cycle:** 1) 20 mM Na-phosphate + 150 mM NaCl, pH 7.4, 15 min, 2) 0.5 M NaOH, 15 min, 3) 20 mM Na-phosphate + 150 mM NaCl, pH 7.4, 15 min, 4) 0.1 M Na-citrate, pH 3.0, 15 min, 5) 20 mM Na-phosphate + 150 mM NaCl, pH 7.4, 15 min

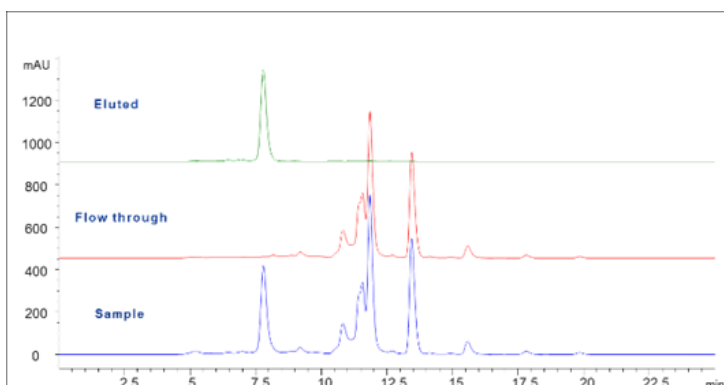
Monoclonal Antibody Purification Application



MabPurix P30 Affinity resin purification on a monoclonal antibody fermentation supernatant

Column: 15 mm x 150 mm; **Sample:** 144.3 ml monoclonal antibody fermentation supernatant, concentration 2.84 mg/mL; **Equilibrium:** 20 mM Na-phosphate, 150 mM NaCl, pH 7.4; **Sample Loading:** 4.123 mL/min (3 min residence time), 35 min loading time; **Wash 1:** 20 mM Na-phosphate, 150 mM NaCl, pH 7.4, **Wash 2:** 20 mM Na-phosphate, 2.0 M NaCl, pH 6.0; **Elution:** 100 mM Gly-HCl, pH 3.0 (add 28.9 mL 1 M Tris-HCl, 144 mL collection in total); **CIP:** 0.5 M NaOH, 15 min; **Re-equilibrium:** 20 mM Na-phosphate, 150 mM NaCl, pH 7.4; **Flow Rate:** in Equilibrium/ Wash/ Elution/ CIP/ Re-equilibrium: 5.0 mL/min

Purification Result Analysis of MabPurix P30 Affinity Resin



Column: Zenix SEC-300, 4.6 x 300 mm; **Mobile Phase:** 150 mM Sodium phosphate buffer, pH7.0 **Flow Rate:** 0.35 mL/min; **Injection Volume:** 10 μ L; **UV Detector:** 280 nm; **Residence Time:** 3 min; **Sample Loading Volume:** 144.5 mL; **Sample Loading Amount:** 409.8 mg (33.1 mg/mL); **Sample Recovered:** 410.6 mg; **Recovery Yield:** >99%; **Purity by SEC:** 94.5%

Ordering Information

Resin	Bead Size (μ m)	Part Number
MabPurix A45	45	270745990
MabPurix A65	65	270765990
MabPurix P30	30	270830990
MabPurix P45	45	270845990

Standard packing sizes: 0.5, 1, 5, 10, 100 L
Standard pre-packed columns: 1, 5 mL

Additional packaging size and pre-packed column dimensions are available.

Better Surface Chemistry For Better Separation



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