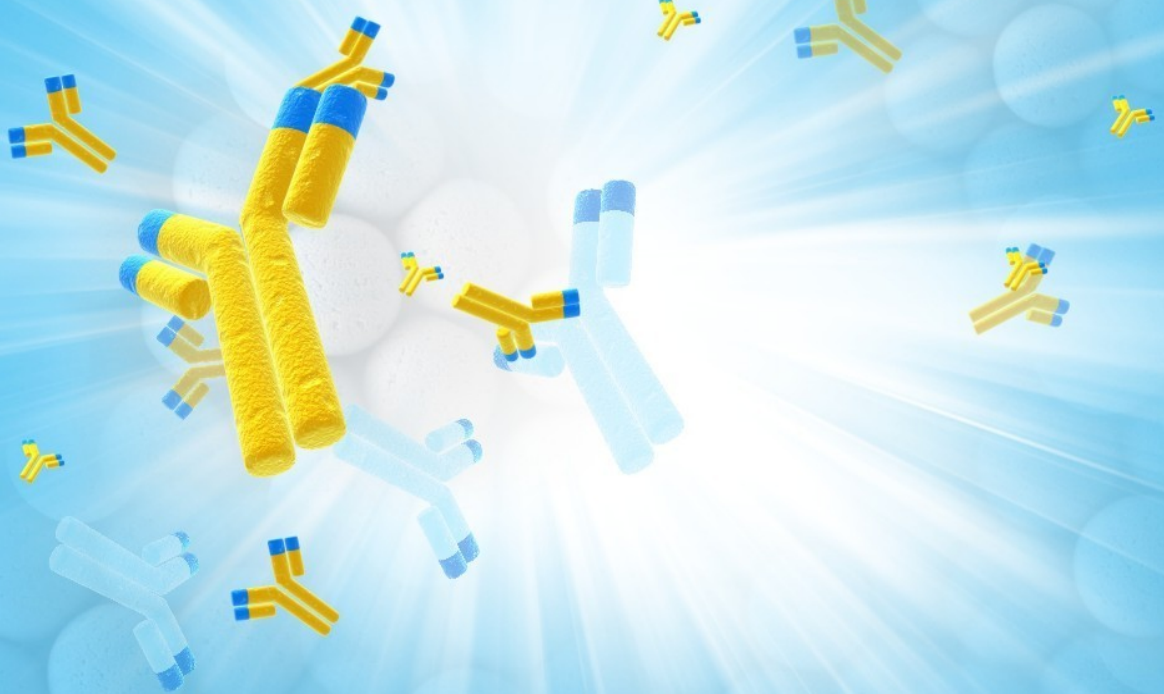
Affinity Chromatography

Sepax Technologies

MabPurix™



Better Surface Chemistry for Better Separation

MabPurix™ – High Performance Protein A Affinity Media

Excellent Choice for Monoclonal Antibody Purification

General Description

Utilizing proprietary surface technologies, MabPurix resin is made of highly cross-linked 4% agarose beads with a particle size of 45-165 µm and a recombinant Protein A with the molecular weight of 46.7 kD. MabPurix Protein A affinity resin is designed to bind and elute monoclonal antibodies (Mabs) in affinity process chromatography for purification of recombinant proteins and Mabs.

MabPurix is applicable at laboratory discovery, process development, clinical and commercial manufacturing scale for processes producing a few mgs to 10's of kilograms of protein. This resin is an excellent purification tool in the manufacturing of both therapeutic and diagnostic proteins.

Featured Characteristics

- High Mab binding capacity
- Lowest Protein A leakage
- Good caustic stability
- Excellent protease stability
- High lot-to-lot reproducibility
- Ideal High protein recovery with intact biological activity
- Negligible non-specific interactions
- Broad applicability from development scale to commercial scale applications

High Dynamic Binding Capacity

Figure 1 shows MabPurix has similar dynamic binding capacity to that of MabSelect SuRe.

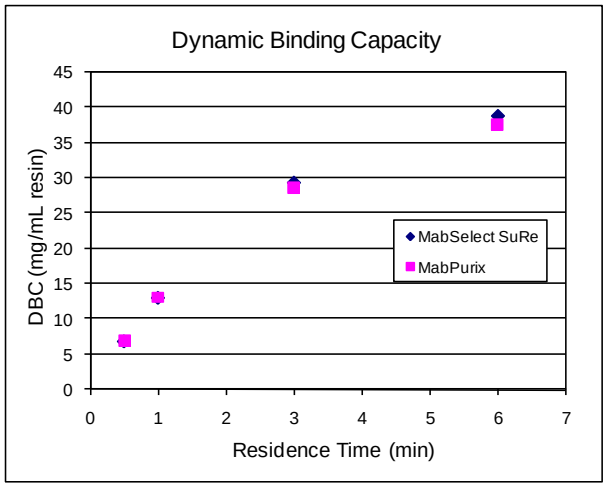


Figure 1. Experimental details: DBC was determined for human polyclonal IgG at 2% breakthrough. Residence times ranging from 0.5 to 6 minutes. A 5 x 50 mm column was loaded with a 2 mg/mL hIgG solution in PBS pH 7.4.

Technical Specifications

Property	Value
Matrix composition	4% Highly cross linked Agarose
Ligand	Recombinant Protein A with the MW of 46.7 kD. IgG binding – E, D, A, B, and C regions. Animal free
Particle size	45 - 165 µm
Coupling chemistry	Proprietary
Binding capacity	Static: >40 mg human IgG/ml resin Dynamic binding capacity at 3 min residence: 33 mg/mL
Caustic stability in 0.1 N NaOH	100 cycles
Protein A leaching	≤ 10 ng/mg IgG
Recommended working velocity	30 - 300 cm/hr
Temperature Stability	2 - 40°C Long term storage: store at 2-8°C in a suitable bacteriostatic agent like 20% Ethanol or 0.02% Sodium Azide. **Protect from freezing.**
Delivery conditions	Shipped at room temperature, 52.0% slurry Containing 18.5% ethanol
Storage conditions	2 - 8°C in the presence of a bacteriostatic agent (e.g. 18.5 - 20% ethanol)
Recommended pH working range	3 - 10 Short term exposure to pH below 3 is sometimes required to elute strongly bound IgG species. However, care must be taken not to denature the protein ligand.
Clean in Place Recommended pH	2 - 11
Regeneration	After each separation cycle, regenerate the resin bed by washing with 3 column volumes of 0.1 M citrate buffer, pH 3.0.

Applications

Caustic Stability Test

MabPurix may be cleaned and sanitized with a weak NaOH solution resulting in a moderate decrease in resin capacity over extended exposure times (Figure 2.). An exposure time of 25 hours represents 100 x 15 minute CIP cycles in 0.1 N NaOH.

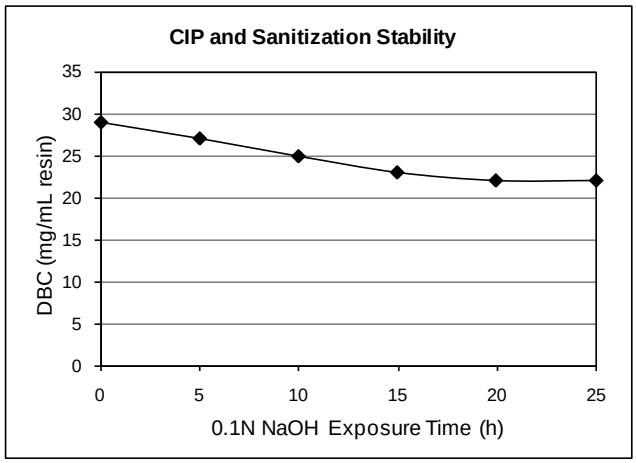


Figure 2. The residual dynamic binding capacity was determined for human polyclonal IgG following 0.1 N NaOH exposure. A 5 x 50 mm column was loaded with a 2 mg/ml hIgG solution in PBS pH 7.4. The loading residence time was 3 minutes. Capacity was determined and reported at 2% breakthrough. Each column elution was followed by 5 h exposure to 0.1 N NaOH.

Process Stability Test

Protease resistance is important for the preservation of binding activity and lower ligand leaching. Due to improved attachment chemistry, MabPurix achieved high protease stability compared to MabSelect SuRe in terms of long term protease stability. After 3h exposure, MabPurix has more than 85% of initial break through capacity remains, as shown in Figure 3.

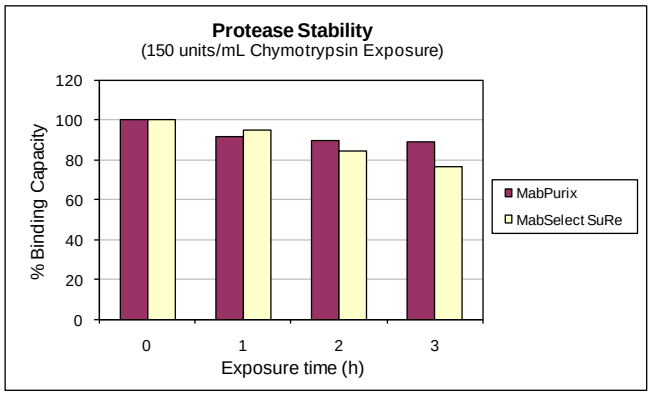


Figure 3. Chymotrypsin was used as a model challenge to evaluate MabPurix resistance to protease induced degradation. 3 x 1 hour exposure cycles. Static binding capacity determined following each cycle.

MabPurix – the Lowest Leaching Media

Protein A leaches from affinity resins as a natural result of protease or caustic degradation of the immobilization chemistry or the ligand itself. Leakage of Protein A from MabPurix is generally very low due to the improved coupling chemistry, as shown in Figure 4.

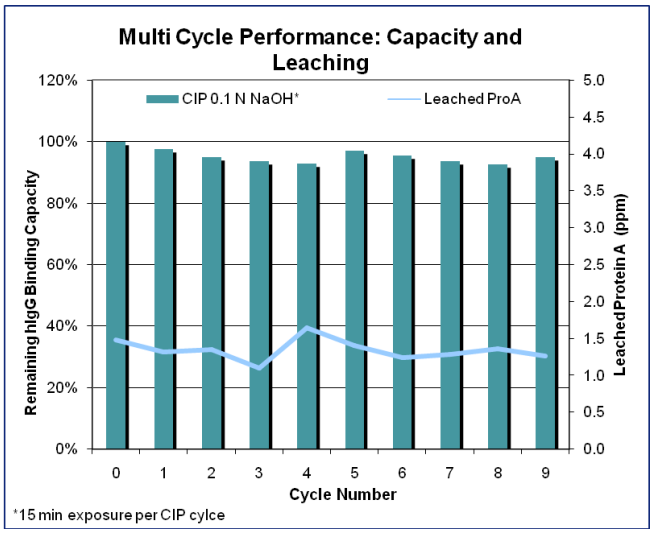


Figure 4. Experimental details: The human polyclonal IgG binding capacity was determined following each column cycle. CIP was performed between cycles with 0.1 N NaOH and a 15 min contact time. Contaminating Protein A was measured in the product pool from each cycle using the commercially available Protein A ELISA Kit.

Product Ordering Information

MabPurix medium is shipped in 18.5±1% ethanol at room temperature.

Description	Unit	Part Number
MabPurix	5 mL	281085-0005
MabPurix	25 mL	281085-0025
MabPurix	100 mL	281085-0100
MabPurix	250 mL	281085-0250
MabPurix	500 mL	281085-0500
MabPurix	1 L	281085-1000
MabPurix	5 L	281085-5000
MabPurix	10 L	281085-010L
MabPurix	25 L	281085-025L
MabPurix	50 L	281085-050L

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