

# MabPurix™ Protein A Affinity Chromatography Resin media and column

*Excellent Choice for Monoclonal Antibody Purification*

- High Quality & Performance
- Significant Cost Saving
- Excellent technical support & collaboration



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# MABPurix

## High Performance + Significantly Reducing Cost

| Specifications                            | MABPurix      | GE MabSelect SuRe |
|---|---------------|-------------------|
| Bead                                      | Agarose       | Agarose           |
| Dynamic Binding Capacity @ 3min Residence | ~ 33 mgs/ml   | ~ 38 mgs/ml       |
| Flow Rate                                 | 300 cm/hr     | 500 cm/hr         |
| Protein A Leaching                        | ~10 ng/mg IgG | ~ 20 ng/mg IgG    |
| Caustic Stability in .1M NaOH             | 100+ cycles   | 100+ Cycles       |

- ✓ **The high capacity protein A resin with a compelling cost advantage**
- ✓ **Broad applicability from development scale to commercial scale applications**



# MABPurix

All Starting Materials Are Commonly Used in Industry

- **Agarose Beads**
  - Equivalent to GE 4FF Agarose beads
- **Recombinant Native Staphylococcal Protein A (rSPA)**
  - Animal Free; produced in *Escherichia coli*
  - An exact amino acid copy of the native *S. aureus* protein A
  - Identical in structure and function to the native Protein A molecule
  - Expression in a highly effective, high titer *E. coli* fermentation
- **Proprietary and Effective Coupling Chemistry**
- **Made under an ISO 9001 quality system**
- **Supported by industry standard Regulatory Support File**



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# MabPurix Performance VS Agarose Based Bead Competition

|  | Sepax<br>MabPurix | rSepharose<br>ProteinA | MabSelect           | MabSelect<br>SuRe   |
|--|-------------------|------------------------|---------------------|---------------------|
| Bead Matrix                                      | 4% Agarose<br>4FF | 4% Agarose<br>4FF      | HC Agarose<br>Rigid | HC Agarose<br>Rigid |
| Static Binding<br>Capacity                       | >40mg/mL          | >40mg/mL               | >40mg/mL            | >40mg/mL            |
| Dynamic Binding<br>Capacity<br>at 3min Residence | ~ 33mg/mL         | ~ 33mg/mL              | ~ 38mg/mL           | ~ 38mg/mL           |
| Protein A<br>Leaching                            | ~10ng/mg IgG      | ~10ng/mg IgG           | ~20ng/mg IgG        | ~20ng/mg IgG        |
| Working<br>flow rate                             | 300cm/hr          | 300cm/hr               | 500cm/hr            | 500cm/hr            |
| Caustic Stability                                |                   |                        |                     |                     |
| 0.05M NaOH                                       | Yes - 100+ Cycles |                        | Yes - No cycles     | Yes                 |
| 0.1M NaOH  | Yes - 100 Cycles  |                        | No                  | 200                 |
| 0.5M NaOH  | No                | No                     | No                  | 80                  |

## MabPurix versus:

### rSepharose

- Almost identical
- Greater caustic stability
- Great Cost savings

### MabSelect

- Lower flow rate
- Greater caustic stability
- Great Cost savings

### MabSelect SuRe

- Lower flow rate
- Less caustic stability
- Great Cost savings



# MabPurix Performance Vs Non-Agarose Based Comparison

|  | Sepax MabPurix    | Prosep Ultra-Plus | Poros MabCaptureA |
|--|-------------------|-------------------|-------------------|
| Bead Matrix                                | 4% Agarose 4FF    | CP Glass          | Polystyrene DVB   |
| Static Binding Capacity                    | >40mg/mL          | >67mg/mL          | >48mg/mL          |
| Dynamic Binding Capacity at 3min Residence | ~ 33mg/mL         | ~ 48mg/mL         | >45mg/mL          |
| Protein A Leaching                         | ~10ng/mg IgG      | ~30ng/mg IgG      | ~50ng/mg IgG      |
| Working flow rate                          | 300cm/hr          | 800cm/hr          | 700cm/hr          |
| Caustic Stability                          |                   |                   |                   |
| 0.05M NaOH                                 | Yes - 100+ Cycles |                   |                   |
| 0.1M NaOH                                  | Yes - 100 Cycles  | No                | 100 Cycles        |
| 0.5M NaOH                                  | No                | No                | No                |

## MabPurix versus:

### Prosep Ultra Plus

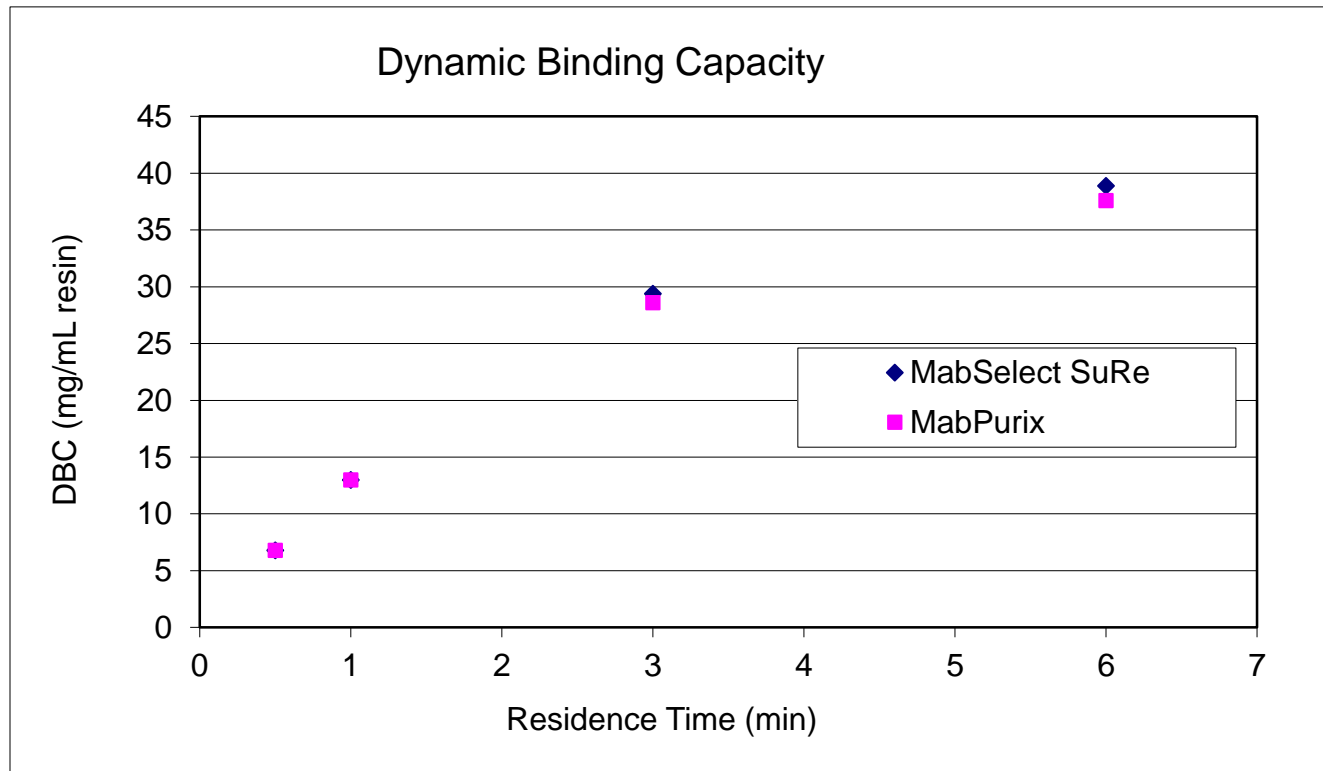
- Lower flow rates
- Caustic stability
- Lower leaching
- Cost savings

### MabCapture A

- Lower flow rates
- Same caustic stability
- Lower leaching
- Cost savings



# MabPurix Capacity: Comparable to MabSelect SuRe



## Experimental:

- Sample: Human polyclonal IgG
- Residence times ranging from 0.5 to 6 min
- Capacity determined at 2% breakthrough
- A column bed height between 10-20 cm, loaded at 100 cm/h, provide 6-12 min of residence time.

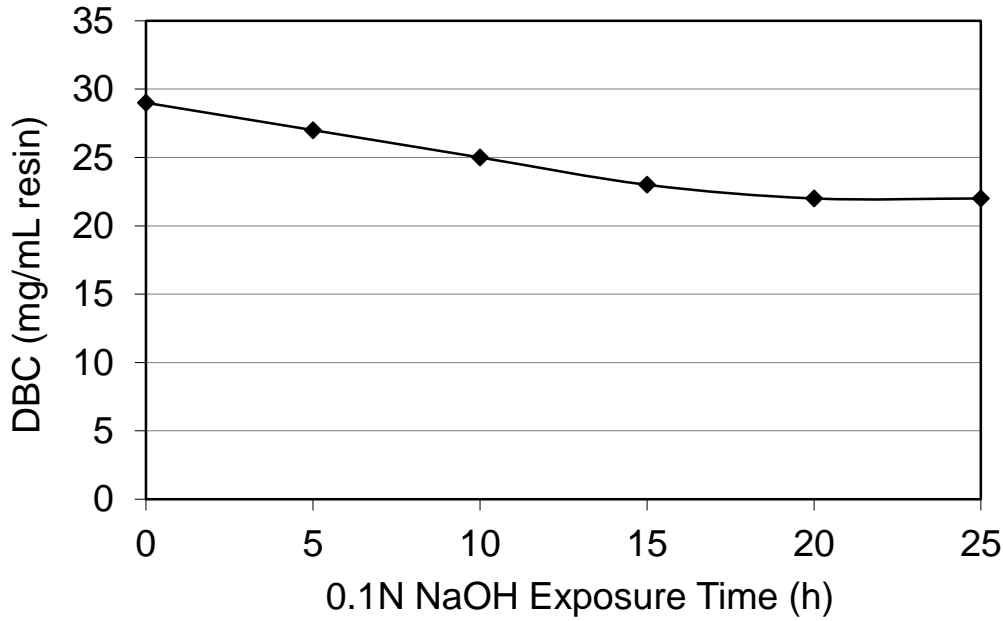


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# MabPurix – High Caustic Stability in 0.1M NaOH for 100 cycles

CIP and Sanitization Stability



- **Retains 80% of initial breakthrough capacities**

Equivalent to > 200 elution cycles

- **Caustic Stability**

MabSelect < MabPurix < MabSelect SuRe

- MabSelect SuRe can withstand 0.5 M

- Few processes use more than 0.05 M NaOH

## Experimental:

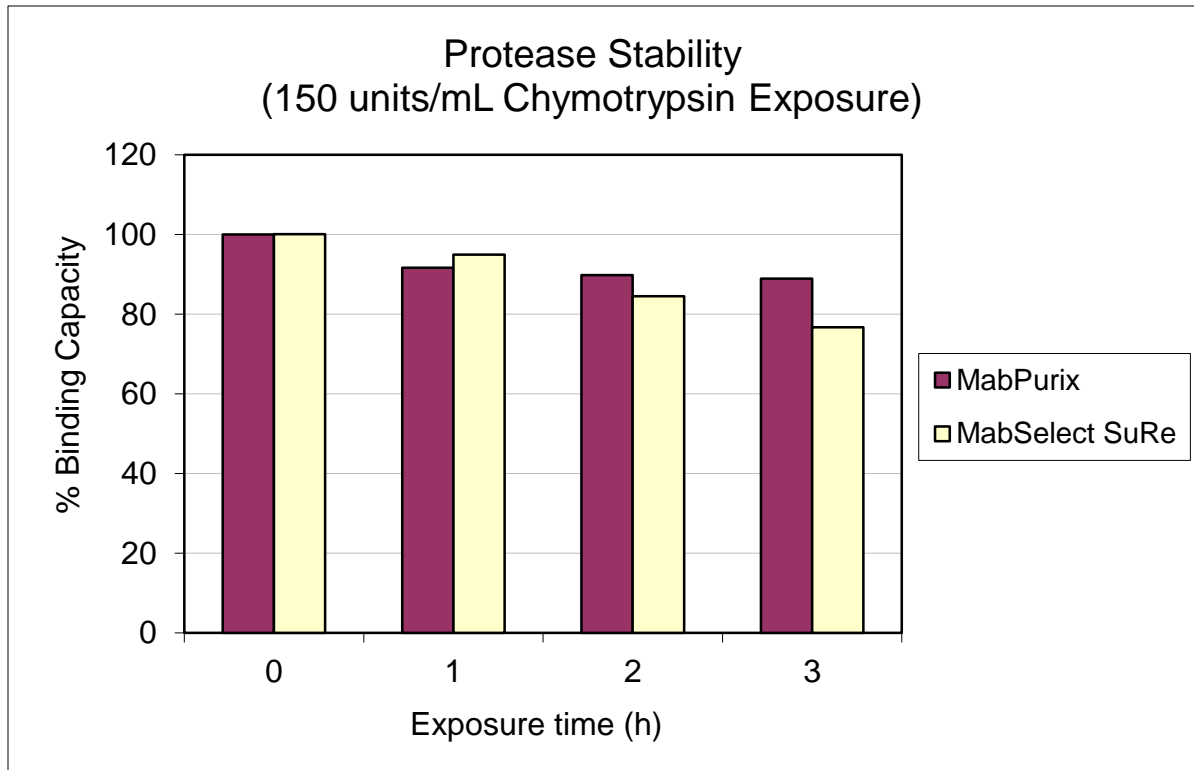
- Residual dynamic binding capacity determined for human polyclonal IgG
- Capacity was determined at 2% breakthrough • Residence time 3 mins
- Post 0.1 M NaOH exposure • Each column elution was followed by a 5 hour exposure to 0.1 M NaOH
- An exposure time of 25 hours represents 100 x 15 minute CIP cycles.



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# MabPurix Process Stability – Protease Stability



## Superior Coupling Chemistry Improves Protease Stability

- After 3 h exposure,  $\geq 85\%$  of initial break through capacity remains
- Protease resistance important for the preservation of binding activity and lower ligand leaching
- MabPurix has higher protease stability compared to MabSuRe

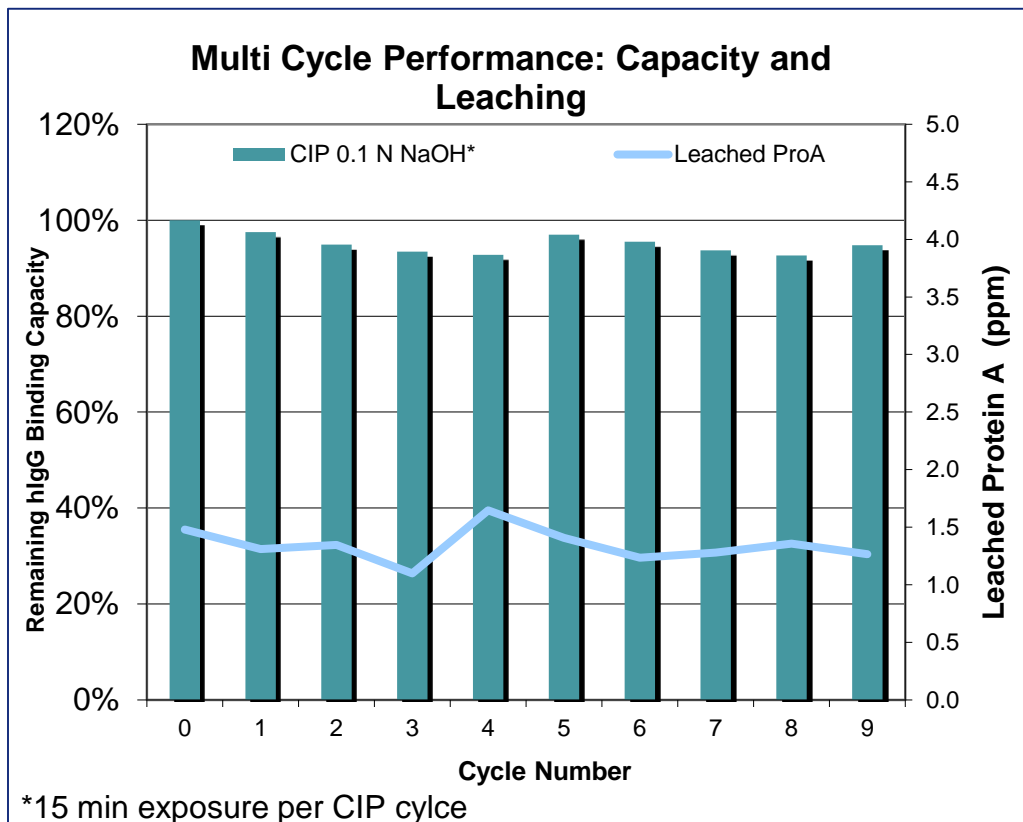
### Experimental

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



# MabPurix is the Lowest Leaching Media

## Experimental Confirmation of Very Low Protein A Leakage



### MabPurix test data shows

- Very low & consistent measured protein A leakage 1-2 ppm (<10 ng/mL)
- No evidence of cycle based increase in protein A leakage
- Regulators require leached protein A testing for lot release
- Criteria set based on therapeutic dose of specific mAb
- Malselect and SuRe 50-80 ng/mL

### Experimental:

The human polyclonal IgG binding capacity was determined following each column cycle. CIP was performed between cycles with 0.1 M NaOH and a 15 min contact time. Contaminating Protein A was measured in the product pool from each cycle using the Leached Protein A ELISA.



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# MabPurix™ Protein A Media – Conclusions

- **Ideal for Clinical Manufacturing & Smaller Commercial Applications**
- **Excellent Chromatographic Performance**
  - Equivalent or better in dynamic binding capacity and ligand leaching
- **Sets new standard for “Value Proposition”**
  - Much better economic value
- **Application Fit**
  - Where extended lifetime applications are not certain
  - Shorter campaign, e.g clinical manufacturing
  - Where high flow rates are not required
- **Similar performance characteristics to MabSelect products except:**
  - Not as high flow rates
  - Not as caustically stable as SuRe™