

# AMSPHERE™ A3

## PROTEIN A RESIN

Alkali Resistant and Optimized Ligand  
for High Capacity

Surface Modified Base Bead  
for High Purity

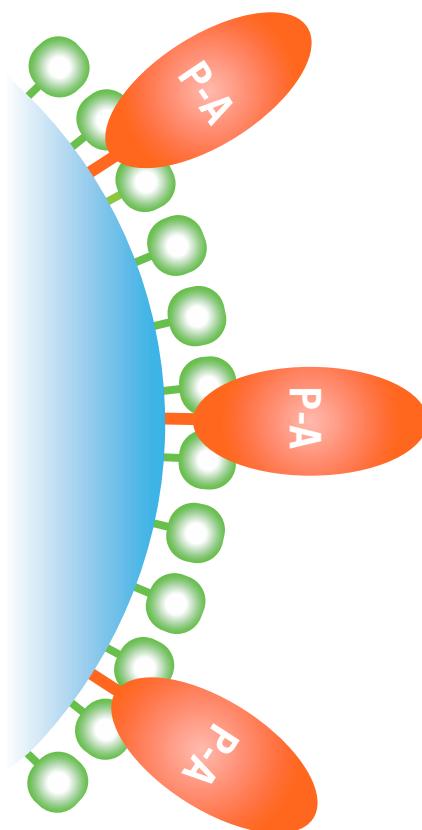
Semi-rigid Bead  
for High Productivity



JSR Life Sciences

# True polymer innovation that bridges amorphous materials and agarose for advanced protein separation.

Protein A chromatography is widely used as the affinity capture step of both mAbs and Fc-fusion proteins because of its high degree of selectivity. Variations in elution behavior of the protein A capture step requires more process development work and could have an impact on the polishing step in the downstream process. Thus minimizing the variation in elution pH between different molecules for example, makes it easier to platform the capture process.



## PROTEIN A LIGAND

- High DBC via controlled conformation and orientation
- High alkaline stability from protein engineering

## SURFACE MODIFICATION AND BASE BEAD FORMULATION

- Low HCP levels by surface hydrophilization
- High DBC at high flow rate
- Good pressure and flow properties via rigid crosslinking

## Outstanding Dynamic Binding Capacity

- 20% - 50% higher DBC compared to market standard product

## Impurity Clearance at Industry Standard

- HCP, aggregate, DNA and virus removal are in-line with market standard product

## Superior Caustic Stability

- More than 100 cycles with 15 mins and 0.1 N NaOH CIP show >90% DBC maintained

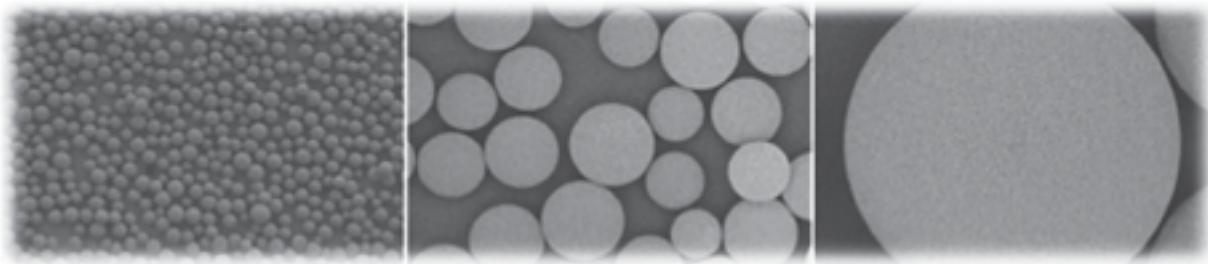
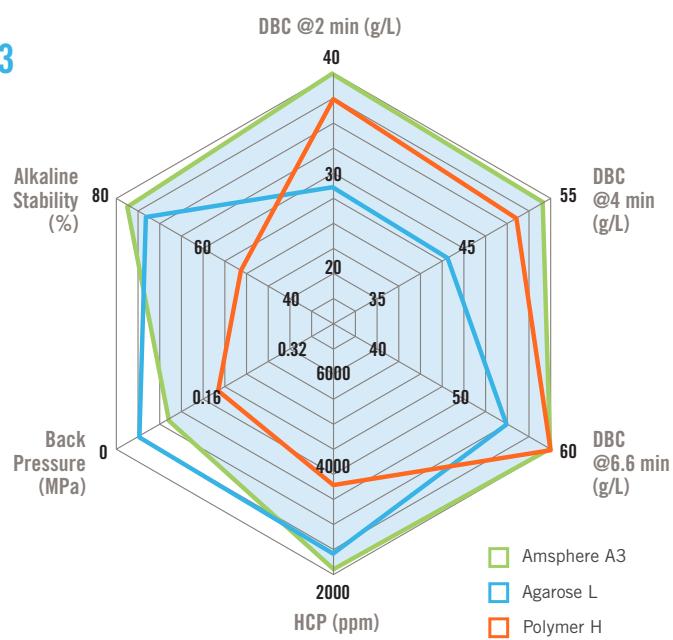
## Good Pressure Flow Properties

- 400 cm/hr at < 3 bar (20 cm BH, 30 cm diameter column)

## Attractive Economics

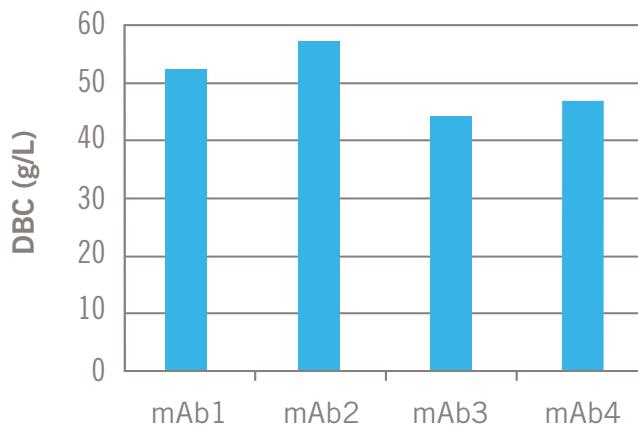
- Thanks to a higher productivity and attractive pricing, Protein A media cost can be reduced by up to 50% compared to market standard product

### Summary of Amsphere™ A3 Features

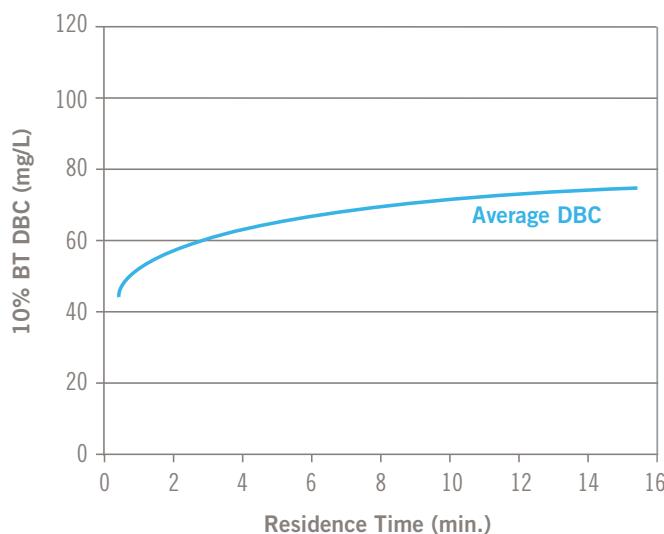


# Dynamic Binding Capacity

mAbs Dynamic Binding Capacities at 5 Minutes



Average Dynamic Binding Capacities of 23 Different mAbs



**CONCLUSION:**  
High binding capacities  
at all flow rates

HPC Clearance

| MOLECULE | HCCF      | ELUATE | LRV  |
|----------|-----------|--------|------|
| mAb1     | 350,000   | 3,100  | 2.05 |
| mAb2     | 220,000   | 1,700  | 2.1  |
| mAb3     | 315,000   | 3,850  | 1.91 |
| mAb4     | 1,170,000 | 1,650  | 2.85 |
| mAb5     | 560,000   | 2,950  | 2.27 |

\*Detection by HCP ELISA (Cygnus F550)

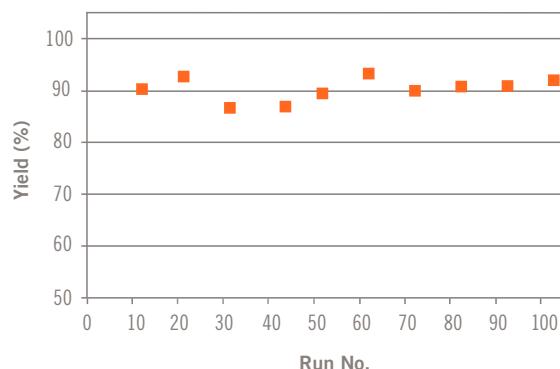
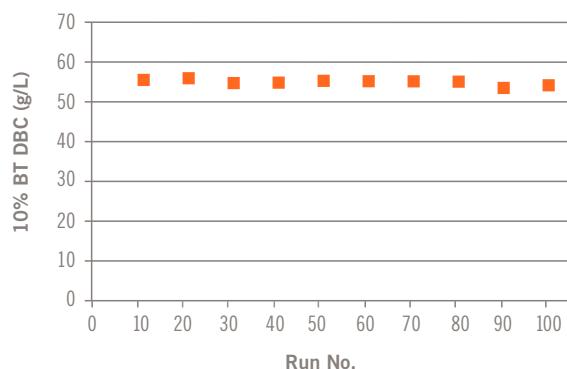
# Alkaline Stability - CIP Cycling

CIP

0.1M NaOH: contact time 30 min

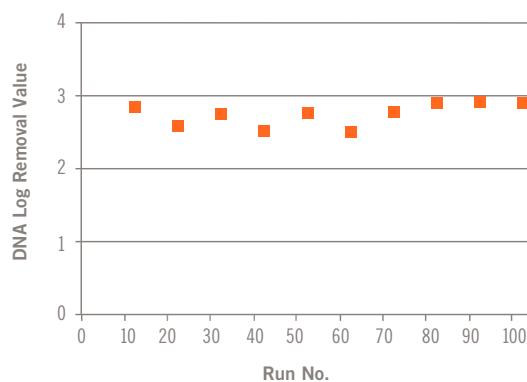
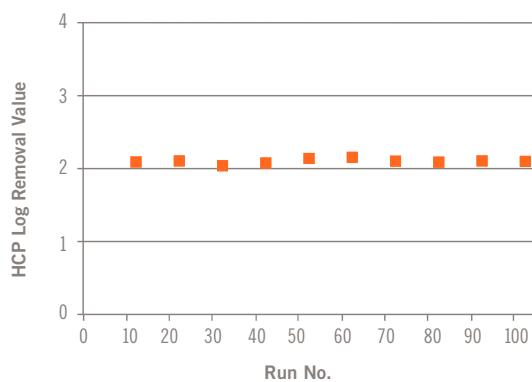
0.5M NaOH: contact time 10 min every 10 cycles

## Dynamic Binding Capacity and mAb Recovery



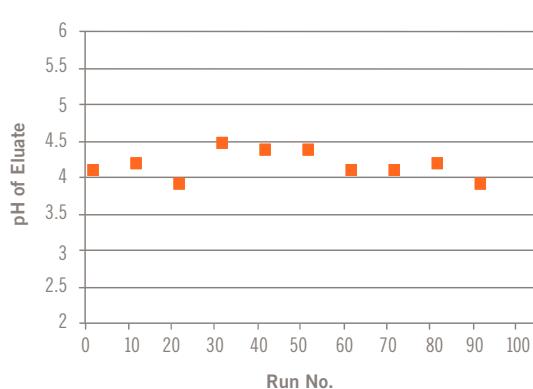
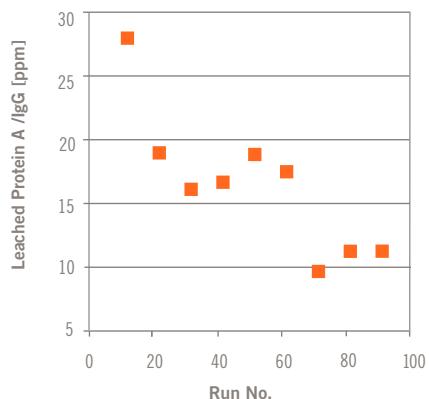
DBC is maintained at initial levels for 100 CIP cycles and Yield is above 90% and constant for 100 CIP cycles

## HCP and DNA Reduction



HCP reduction is approximately 2.0 LRV and is constant for 100 CIP cycles; DNA LRV is consistent at approximately 2.9 throughout the 100 CIP cycles

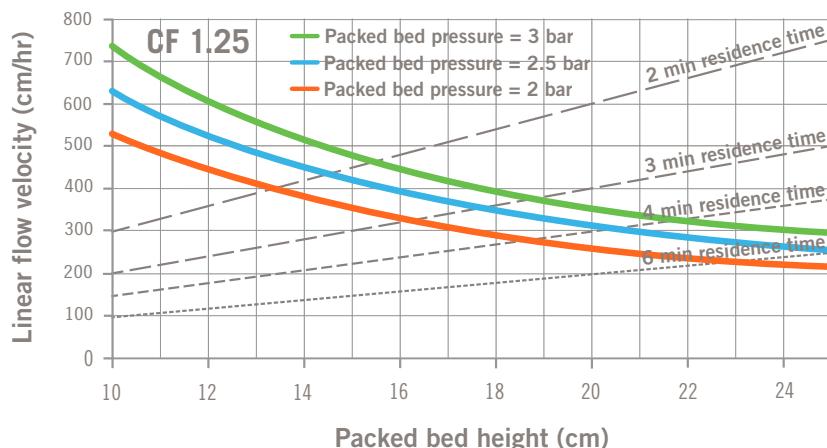
## Protein A Leaching and pH of Eluate



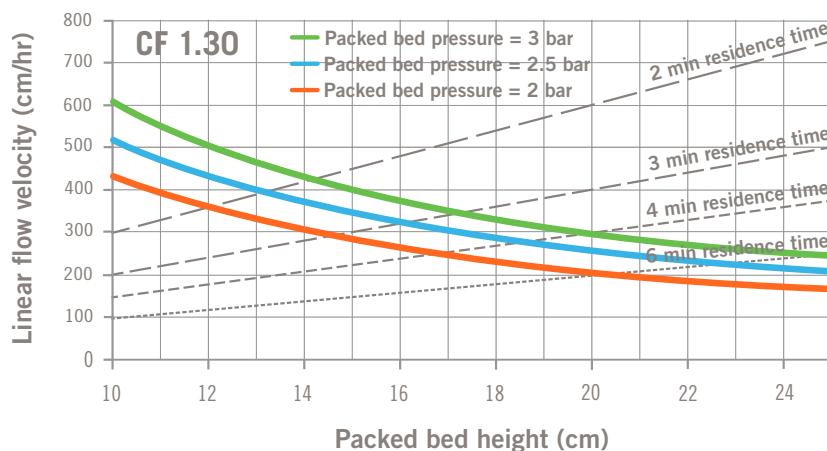
Leached protein A drops to 10-20 ppm after 100 CIP

There are some points under 15ppm; Elution pool pH as a function of run number is stable at approximately 4.0 - 4.5

## Pressure-Flow Properties

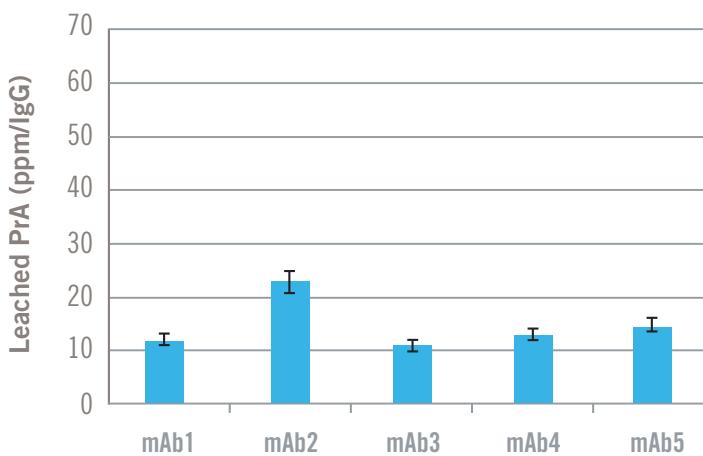


Operating regions  
(20cm column i.d., CF 1.25)



Operating regions  
(20cm column i.d., CF 1.30)

## Protein A Leaching



\*Detection by Protein A ELISA (Cygnus F740)

# Protein A Mix-N-Go ELISA kit



Tailored Protein A ELISA  
kit is available from  
Cygnus Technologies

Protein A Mix-N-Go ELISA kit  
for JSR Life Sciences Ligand  
(Catalog # F740)

[http://www.cygnustechnologies.com/product\\_detail/protein-a-mix-n-go-elisa-kit-jsr.html](http://www.cygnustechnologies.com/product_detail/protein-a-mix-n-go-elisa-kit-jsr.html)

## Technical Properties

| Description                                  |  |
|--|--|
| <b>Product name</b>                          | Amsphere™ A3   |
| <b>Matrix</b>                                | Methacrylic polymer  |
| <b>Average particle size</b>                 | 50 µm  |
| <b>Ligand</b>                                | Recombinant protein A  |
| <b>Dynamic binding capacity<sup>*1</sup></b> | Approximately 54 mg/mL for polyclonal IgG                    |
| <b>Maximum operating pressure</b>            | 0.8 MPa <sup>*2</sup>  |
| <b>Maximum operating velocity</b>            | 1200 cm/h (dependent on column size)                         |
| <b>Recommended bed height</b>                | 5 - 25 cm  |
| <b>Working pH range</b>                      | 1 - 13   |
| <b>Cleaning-in-Place stability</b>           | 0.1 - 0.5 M NaOH   |
| <b>Recommended storage buffer</b>            | 20 mM sodium phosphate buffer containing 16% Ethanol, pH 7.5 |

<sup>\*1</sup> Determined at 10% breakthrough under linear velocity of 300 cm/h in a column with bed height of 20 cm.

<sup>\*2</sup> Do not exceed the column's pressure resistance.

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free sample by  
sending an email to  
your sales agent.  
(see contact details  
on back page)



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