AMSPHERE™ A3

PROTEIN A RESIN

Alkali Resistant and Optimized Ligand
for High Capacity

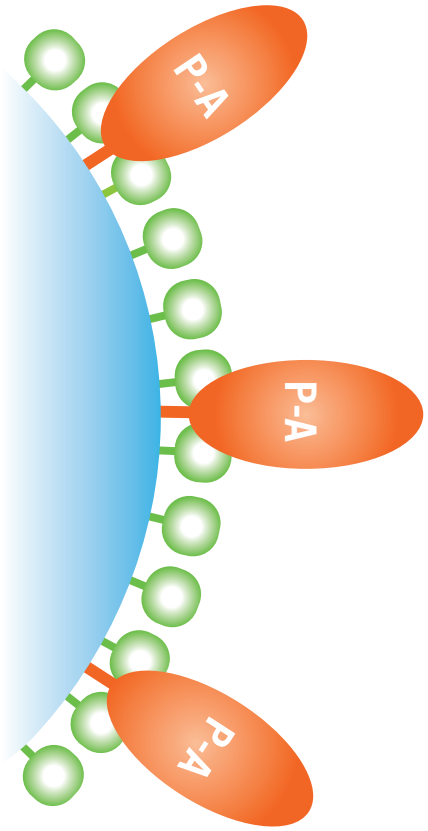
Surface Modified Base Bead
for High Purity

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

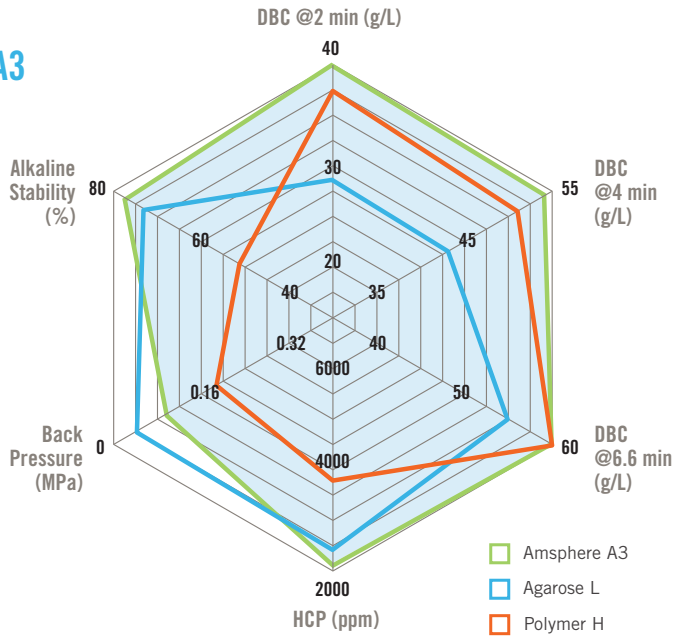
Good Pressure Flow Properties

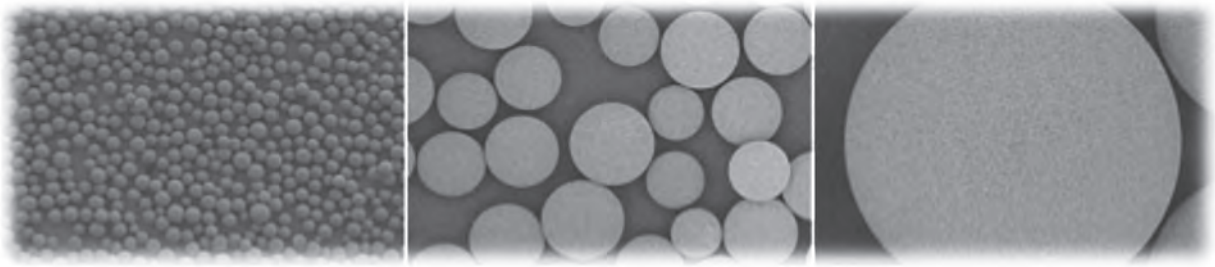
- 400 cm/hr at < 3 bar (20 cm BH, 30 cm diameter column)

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

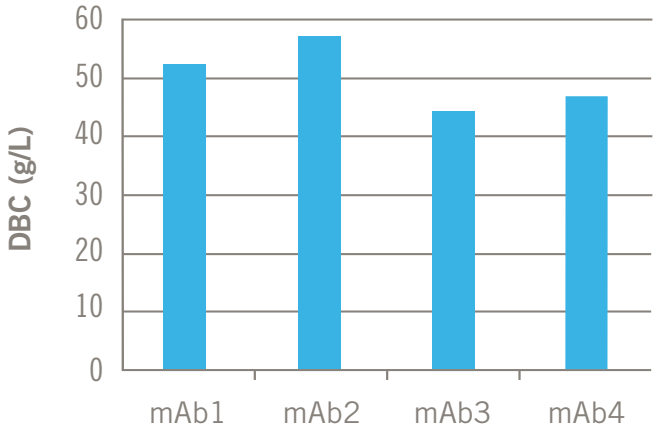
Summary of Amsphere™ A3 Features



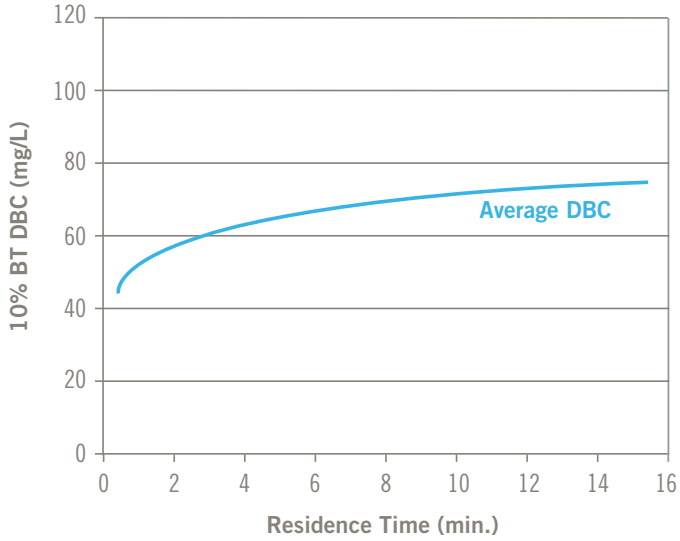


Dynamic Binding Capacity

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

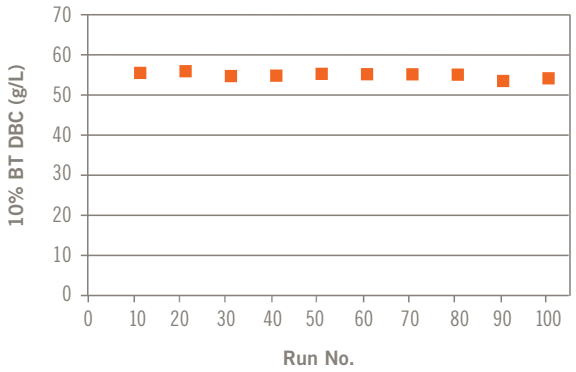
MOLECULE	HCCF	ELUATE	LRV
mAb1	350,000	3,100	2.05
mAb2	220,000	1,700	2.1
mAb3	315,000	3,850	1.91
mAb4	1,170,000	1,650	2.85
mAb5	560,000	2,950	2.27

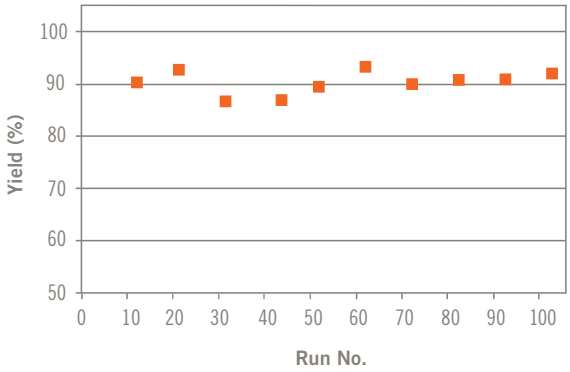
**Detection by HCP ELISA (Cygnus F550)*

Alkaline Stability - CIP Cycling

CIP
0.1M NaOH: contact time 30 min
0.5M NaOH: contact time 10 min every 10 cycles

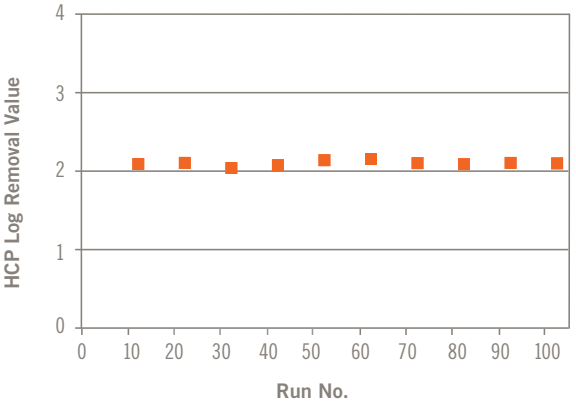
Dynamic Binding Capacity and mAb Recovery

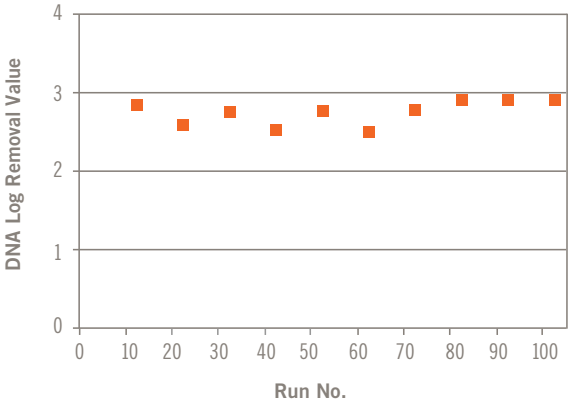




DBC is maintained at initial levels for 100 CIP cycles and Yield is above 90% and constant for 100 CIP cycles

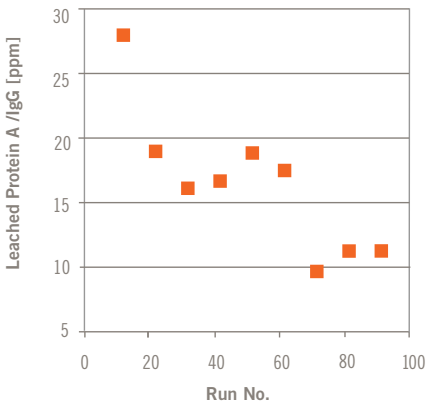
HCP and DNA Reduction

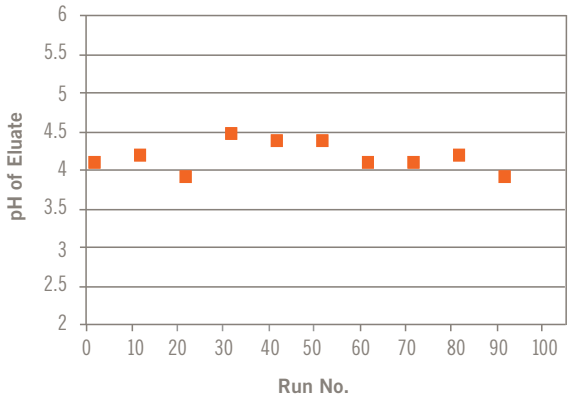




HCP reduction is approximately 2.0 LRV and is constant for 100 CIP cycles; DNA LRV is consistent at approximately 2.9 throughout the 100 CIP cycles

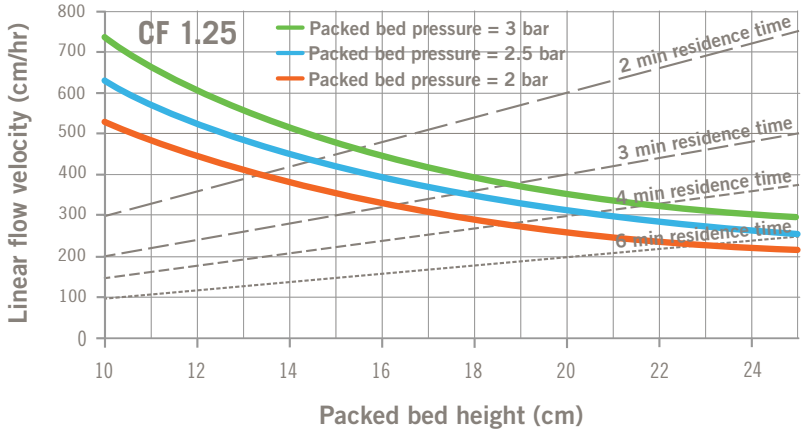
Protein A Leaching and pH of Eluate



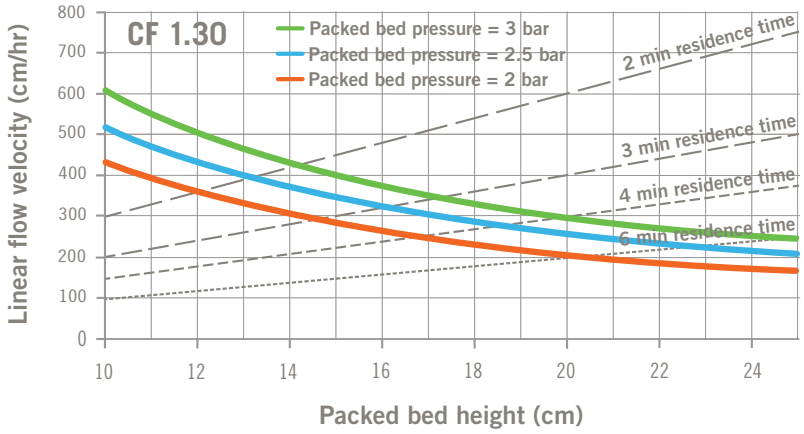


Leached protein A drops to 10-20 ppm after 100 CIP
There are some points under 15ppm; Elution pool pH as a function of run number is stable at approximately 4.0 - 4.5

Pressure - Flow Properties

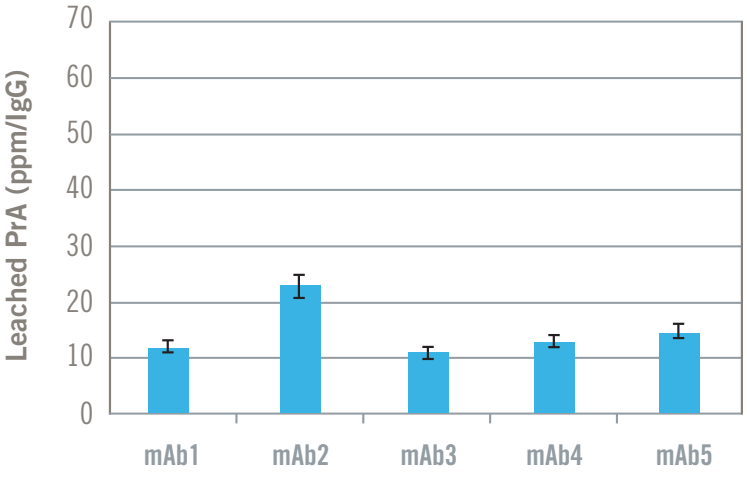


Operating regions
(20cm column i.d., CF 1.25)



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

Technical Properties

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

*[1] Determined at 10% breakthrough under linear velocity of 300 cm/h in a column with bed height of 20 cm.
*[2] Do not exceed the column's pressure resistance.

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

For more information visit www.jsrlifesciences.com

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