

MabSelect™ SuRe 70 protein A resin

AFFINITY CHROMATOGRAPHY

MabSelect™ SuRe 70 protein A resin (Fig 1) enables highly cost-efficient capture of monoclonal antibodies (mAbs) when using a limited number of cycles. MabSelect SuRe 70 resin has the highest dynamic binding capacity (DBC) of any of our MabSelect SuRe resins, and its DBC at shorter residence times (RT) (2.4 to 4 min) is higher than that of MabSelect Prisma™ resin. Together, these features make it especially suited to applications that require high productivity using short bed heights, such as rapid cycling chromatography (RCC). The resin uses the well-established, alkali-stable protein A ligand as used in the MabSelect SuRe resin. It can be cleaned with 0.1 to 0.5 M NaOH, reducing risk for bioburden incidents and providing robust and stable processing of mAbs. The MabSelect SuRe 70 resin is part of the Cytiva mAb resin toolbox, which provides a range of capture and polishing resins for clinical and commercial-scale mAb production.

Key features of MabSelect SuRe 70 resin

- Cost-efficient at low resin utilization, such as in clinical manufacturing.
- High DBC, higher than 70 g/L in a well-packed column at 6 min RT, for efficient resin use.
- Alkali-stable, well-established protein A ligand, from the MabSelect SuRe resin, is stable when cleaned with 0.1 M NaOH for 200 cycles and approximately 100 cycles using 0.5 M NaOH.
- Excellent for use in short bed heights and RCC mode to further improve productivity in protein A step.

Production of mAbs is performed across a wide range of scales, from research and process development in the lab, to preclinical and clinical production, all the way to commercial scale production. The scale of operation, mode of operation, and batch frequency will determine the optimal protein A resin for a given process. During clinical operation, where the number of batch runs is typically 10 or fewer, resins made for large-scale manufacturing are rarely used to their full lifetime. Instead of paying for this unneeded longevity, manufacturers of few batches may prefer alternatives that provide comparable performance over shorter lifetime.

MabSelect SuRe 70 resin is a cost-efficient alternative for mAb capture, ensuring a robust process so you can focus on the output for the clinical study. MabSelect SuRe 70 resin is excellent for running RCC, as the high DBC is realized at short RT.



Fig 1. MabSelect SuRe 70 protein A resin is available in bulk and in prepacked columns.

Table 1. Main characteristics of MabSelect SuRe 70 protein A resin

Matrix	Highly cross-linked agarose, spherical
Ligand	Alkali-stable protein A-derived (<i>E. coli</i>)
Ligand coupling	Single-point attachment
Coupling chemistry	Epoxy
Particle size d_{50v} *	50 μ m
DBC $QB_{10\%}$ †	> 70 mg mAb/mL resin at 6 min RT > 65 mg mAb/mL resin at 4 min RT
Recommended maximum operating flow velocity‡	220 cm/h (20 cm bed height), 400 cm/h (10 cm bed height)
Chemical stability	Stable in aqueous buffers commonly used in protein A chromatography
pH stability, operational§	3 to 12
pH stability, CIP¶	2 to 13.7
CIP stability¶	0.1 to 0.5 M NaOH
Delivery conditions	20% ethanol

* Median particle size of the cumulative volume distribution

† DBC at 10% breakthrough by frontal analysis using trastuzumab at a RT of 6 min (100 cm/h).

‡ Analysis performed in a HiScreen™ column at 10 cm bed height

§ In an AxiChrom™ 300 column with 30 cm i.d. packed according to verified methods, when operated in an aqueous solution with a viscosity of 1 cP at 20°C.

¶ pH range where resin can be operated without significant change in function

¶ pH range where resin can be subjected to cleaning-in-place (CIP), 0.1 M NaOH without significant change in function, 0.5 M NaOH can be used with some loss in capacity

This enables increased productivity and high resin utilization. MabSelect SuRe 70 resin uses the same protein A ligand as our well-established MabSelect SuRe and MabSelect SuRe LX resins. It can also use the same analytical methods and qualification methods to save time during implementation. This range of resins is widely used in regulatory-approved processes and builds on decades of experience in commercial GMP operations. Table 1 summarizes the characteristics of this resin.

Productivity in the mAb capture step

A productive capture step will maximize the outputs of your process while minimizing inputs required in the form of raw materials. Critical productivity parameters may be processing time, consumable cost per gram of mAb, or output of your existing facility. Resin-related parameters such as DBC, flow properties, column diameter, alkaline stability, and resin cost, all effects the productivity. Cytiva can support you in a discussion about how to make your process more cost efficient. [Contact us for a productivity discussion.](#)

DBC at different residence times

The MabSelect SuRe 70 resin is based on a high-flow agarose base matrix with an median bead size of 50 μm . The optimized porosity enables a fast uptake of mAb, and the DBC is less dependent on RT compared to other resins (e.g., MabSelect SuRe LX and MabSelect PrismaA resins). As shown in Figure 2, the DBC for MabSelect SuRe 70 resin using trastuzumab is significantly higher than that of MabSelect SuRe LX resin at all RTs tested, and is higher than that of MabSelect PrismaA resin at shorter RTs.

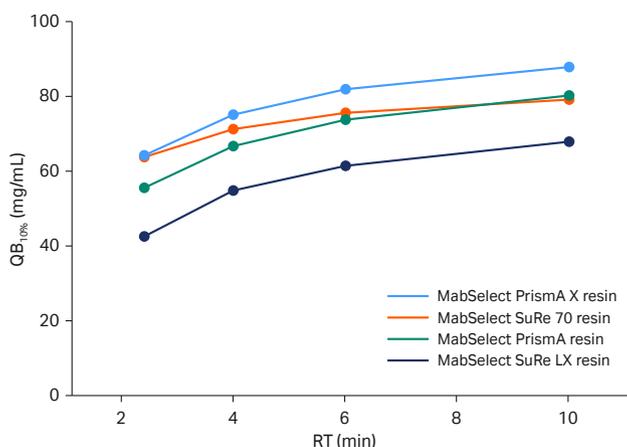


Fig 2. DBC, $QB_{10\%}$, for MabSelect SuRe 70, MabSelect SuRe LX, MabSelect PrismaA, and MabSelect PrismaA X resins in a HiScreen column at 10 cm bed height using trastuzumab at different RTs.

High flow rates at short bed heights

The working range in respect to flow velocity for MabSelect SuRe 70 resin at 20 cm bed height is up to 220 cm/h in an AxiChrom column packed according to verified methods, when operated in an aqueous solution with a viscosity of 1 cP at 20°C. At 10 cm bed height the flow velocity can be increased to approximately 400 cm/h corresponding to 1.5 min RT (Fig 3). The resin is well suited for high-flow applications in short bed heights such as RCC mode.

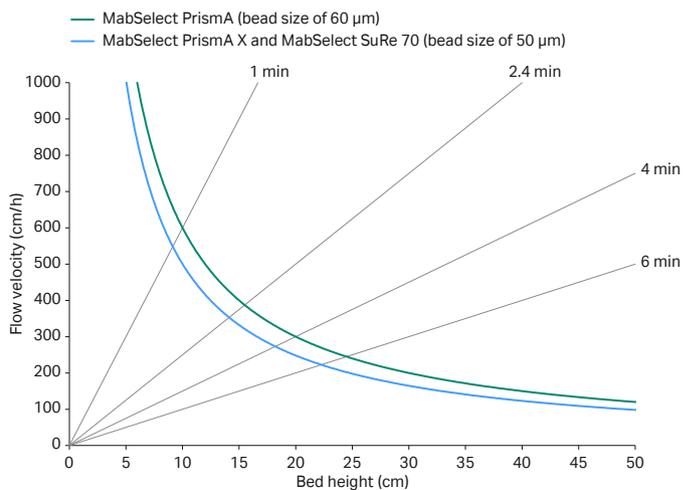


Fig 3. The flow velocity that can be used for a given resin increases with decreasing bed height, enabling faster runs at short bed heights. In an AxiChrom column with i.d. > 30 cm packed according to verified methods, when operated in an aqueous solution with a viscosity of 1 cP at 20°C.

Alkali-stable protein A ligand

To prevent fouling of a resin and to minimize risk of bioburden, it is important to have an efficient cleaning protocol, which means that the resin must tolerate alkaline conditions. As native protein A is sensitive to alkaline conditions, the ligand in MabSelect SuRe 70 resin, also used in the MabSelect SuRe resin, has been stabilized by engineering one of the IgG-binding domains of protein A.

The resin may be cleaned repeatedly with 0.1 to 0.5 M NaOH without performance loss shown in an accelerated alkaline stability study. In the accelerated alkaline stability study, the column was exposed to NaOH for 4 h (corresponding to 16 cycles of 15 min duration each). The incubation was repeated multiple times. The dynamic binding capacity was measured with trastuzumab, and the relative remaining capacity was calculated between incubations. As Figure 4 shows, the lower concentration range, 0.1 M NaOH, can be used for 200 cycles. For 100 cycles, sufficient for clinical production, the resin can withstand 0.5 M NaOH. Accelerated studies provides quick alkaline stability results, however CIP cycling studies with the relevant target molecule needs to be performed for full understanding of the alkaline stability.

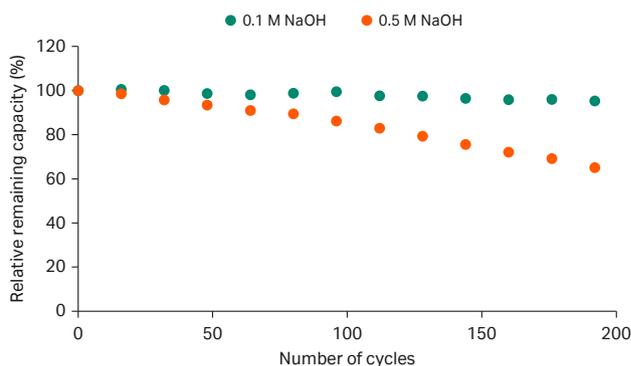


Fig 4. A study of accelerated alkaline stability for MabSelect SuRe 70 resin showed that the resin can be used for 200 cycles at 0.1 M NaOH and for 100 cycles at 0.5 M NaOH with more than 80% relative remaining capacity.

Different protein A productivity scenarios

Thanks to extensive reuse, protein A resin costs are typically relatively low in commercial manufacturing. To reduce protein A resin costs in clinical scenarios where resin lifetime utilization is limited, RCC may be used. Figures 5 and 6 show different scenarios (simplified here for clarity) in clinical (five batches) and commercial (full resin utilization) manufacturing using MabSelect SuRe 70 resin for short bed heights and high titers (see Table 2 for process parameters).

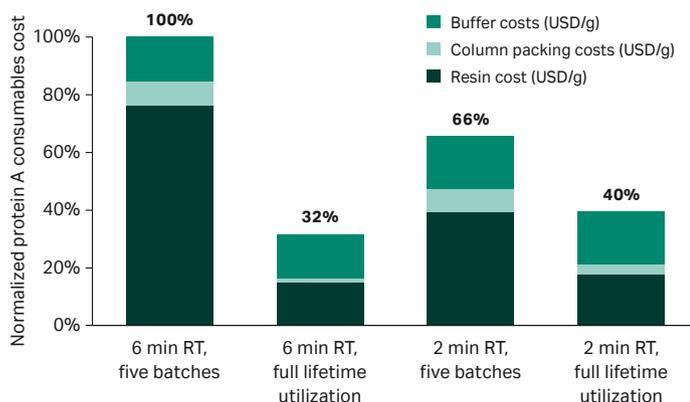


Fig 5. Normalized protein A consumable cost using the protein MabSelect SuRe 70 protein A resin for five batches and utilizing the full lifetime, respectively, at 6 min and 2 min RT. Resin and column packing cost per gram of mAb produced is calculated based on the number of cycles used. Using short RT will reduce resin cost at low resin lifetime utilization and increase costs at high lifetime utilization.

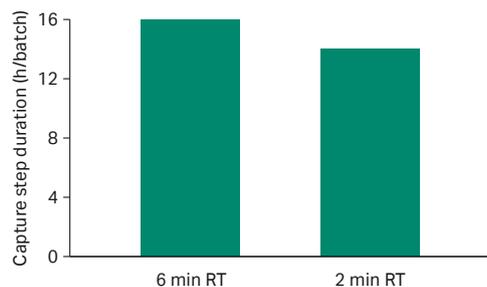


Fig 6. Duration of the MabSelect SuRe 70 protein A chromatography step decreases with shorter RT, despite more cycles being run with smaller column volumes. Resin utilization does not impact the times required to run a batch.

Table 2. Process parameters

Parameter	6 min RT		2 min RT	
	Five batches	Full lifetime	Five batches	Full lifetime
Resin utilization	Five batches	Full lifetime	Five batches	Full lifetime
Volume clarified cell culture feed	2000 L			
Titer	4.25 g/L			
Column diameter	45 cm			
Column bed height	20 cm		10 cm	

Resin and column formats

MabSelect SuRe 70 resin is available as bulk resin in 25 mL, 200 mL, 1 L, 5 L, and 10 L containers. The resin can be ordered in pre-packed column formats such as HiTrap™ columns (1 and 5 mL), HiScreen columns, and on request as production scale ReadyToProcess™ columns. These formats enable use from lab-scale to commercial-scale manufacturing.

Determining ligand leakage

Leakage of the MabSelect SuRe 70 protein A ligand can be measured using a commercial ELISA kit developed for the detection of this specific ligand. We offer free MabSelect SuRe 70 ligand for ligand leakage determination.

Recommended protocol

Table 3 outlines a typical mAb capture process using MabSelect SuRe 70 resin.

Table 3. Typical protein A capture protocol

Step	Column volume (CV)	RT (min)/linear flow velocity (cm/h) at 20 cm bed height	Buffer
Equilibration	3	6/200	20 mM sodium phosphate, pH 7.4 + 150 mM NaCl*
Load	70% to 80% of QB _{10%}	6/200	As required
Wash 1	5	6/200	20 mM sodium phosphate, pH 7 + 500 mM NaCl
Wash 2	1	6/200	50 mM sodium acetate, pH 6
Elution step	3	6/200	50 mM sodium acetate, pH 3.5
Strip	2	6/200	100 M acetic acid, pH 2.9
CIP [†]	3 (≥ 15 min contact time in upflow)	5.5/220	0.1 M NaOH to 0.5 M NaOH
Re-equilibration	3 to 5 (in upflow)	5.5/220	20 mM sodium phosphate, pH 7.4 + 150 mM NaCl*
Only after last run/for storage	4	7.5/160	20% ethanol

* For lab-scale use, 20 mM sodium phosphate, pH 7.4 + 500 mM NaCl can be used also for equilibration and reequilibration to reduce the number of different buffers.

[†] MabSelect SuRe 70 resin cannot be cleaned using 3 CV of CIP solution with a contact time of 15 min (5 min residence time) when the column bed height exceeds 18.7 cm due to flow limitations of the resin. For columns with greater bed heights, increase the contact time as needed.

Resin storage

MabSelect SuRe 70 resin is delivered in 20% ethanol. Store unused resin in its container between 2°C to 8°C. Ensure that the screw top is fully tightened. Equilibrate packed columns in buffer containing 20% ethanol or 2% benzyl alcohol to prevent microbial growth. After storage, equilibrate with starting buffer and perform a blank run, including CIP, before use.

Cytiva's mAb toolbox

Process volumes, number of batches, target molecule, and cleaning protocols influence which protein A affinity chromatography resin will be most cost-efficient and productive in a given application. Figure 7 shows different protein A resins and what to consider to develop a cost-efficient protein A step. All Cytiva MabSelect protein A resins are suitable for large-scale manufacturing and our ligands and base matrices are widely used in commercial manufacturing.

The protein A affinity capture step in antibody purification is followed by one or two polishing steps to remove impurities. [Learn more about our Capto™ resins](#) used in polishing steps.

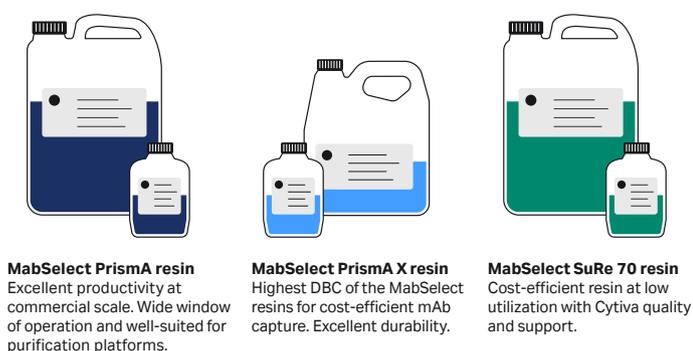


Fig 7. Protein A resins for different process scenarios.

Supply chain stability

We recognize the critical importance of reliable and secure supply to you. We are rapidly expanding our robust manufacturing capacity and maintaining open communication with you to support supply resilience.

We recommend that you work closely with your Cytiva representative to forecast demand to support our production planning and manufacturing operations.

Find out more about how we support [secure supply to the biopharma industry](#).

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CY49304-23Feb26-DF

Support and training

MabSelect SuRe 70 resin belongs to the BioProcess™ family of products developed and supported for large-scale manufacture of biopharmaceuticals. This support includes validated manufacturing methods, secure long-term resin supply, and regulatory support files (RSF) to assist process validation and submission to regulatory authorities. In addition, Fast Trak™ training and education provide high-level, hands-on training in key aspects of process development and manufacturing. Use [Cytiva online learning](#) to build your skills and continue your education.

Ordering information

Product	Size	Product code
HiTrap MabSelect SuRe 70 column	1 × 1 mL	17542411
	5 × 1 mL	17542412
	1 × 5 mL	17542413
	5 × 5 mL	17542414
HiScreen MabSelect SuRe 70 column	1 × 4.7 mL	17542410
PreDictor™ RoboColumn MabSelect SuRe 70 column	8 × 200 µL	17542433
	8 × 600 µL	17542434
MabSelect SuRe 70 resin	25 mL	17542401
	200 mL	17542402
	1 L	17542403
	5 L	17542404
	10 L	17542405
ReadyToProcess MabSelect SuRe 70 columns	See sizes and product codes	



Please [contact us](#) to request samples of MabSelect SuRe 70 resins.