

**Anion Exchange Resins** 

— Sepax Technologies, Inc. —





### Sepax Monomix Mab60-Q Resin



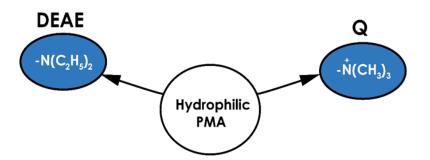
Sepax Monomix Mab60-Q and Monomix HC60-DEAE Excel, is based on hydrophilic treated polymethacrylate. The resins have particle size of 60 µm, and pore size of 1000 Å, with excellent physical and chemical stability.

The resin has tentacle structure that are compose of long linear polymer chains carrying functional groups. The polymer chains are covalently bonded to the matrix, and this configuration provides a high surface area that allows biomolecules to bind accessible functional groups without much steric hindrance.

#### **Characteristics:**

DBC is over 80% of initial value after exposure to **1M NaOH** for over 170 hours

- 1. Improved Alkaline Resistance Longer Lifetime for Reduced Cost
- 2. Lower Working Pressure Easier to Scale Up
- 3. Higher Protein Recovery Higher Yield
- 4. Faster to Reach pH Equilibrium Higher Efficiency





## **Technical Specification**



Туре	Monomix Mab60-Q		
Matrix	Hydrophilic polymethacrylate		
Characteristic	Low pressure High alkaline resistance		
Functional Group	-N <sup>+</sup> (CH <sub>3</sub> ) <sub>3</sub>		
Average particle size (D <sub>50</sub> )	60 μm		
Average pore size	1000 Å		
Dynamic loading capacity (/mL of resin)	≥ 80 mg BSA		
pH stability	2-13		
CIP condition	0.5-1.0 M NaOH		
Maximum operating pressure	10 bar		
Storage	50% (v/v), stored in 20% ethanol or 10 mM in NaOH aqueous solution		
Chemical stability	Suitable for buffer salt system, conventional organic phase/water system		





1. Alkaline Resistance Test

2. Pressure-Linear Flow Rate Test

3. Non-specific binding (NSB) Test

4. Application: Bispecific Antibody-HCP Removal





### Alkaline Resistance Challenge Test

#### Sample retention time change after the resin is soaked with 1 M NaOH

Name	Monomix Mab60-Q							
Soak time /h	RT1/min	R (RT1) %	RT2/min	R (RT2) %				
Before soaking	23.99	/	33.07	1				
48	23.68	98.71	33.03	99.88				
120	23.75	99.00	32.98	99.73				
240	23.40	97.54	32.79	99.15				

#### DBC change after the resin is soaked with 1 M NaOH

Name	Monomix Mab60-Q				
Soak time /h	DBC/ g/L	R(DBC)%			
Before soaking	89.41				
48	86.98	97.28			
120	91.40	102.23			
240	82.55	92.33			

After the **240-hour** soaking test with **1M NaOH**,

the retention time of protein standard did not change essentially and

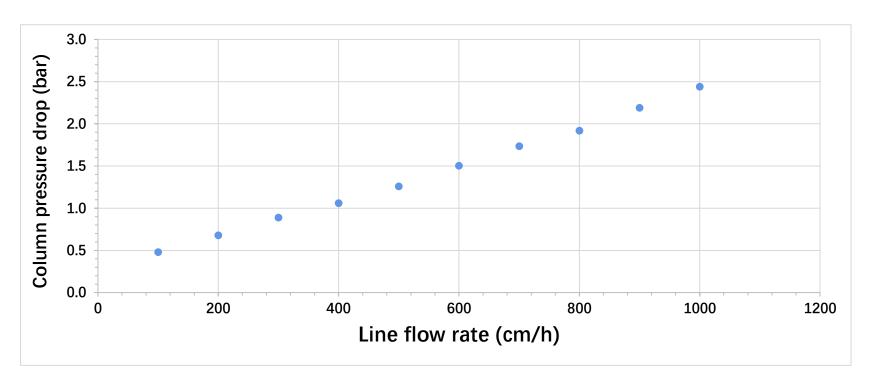
DBC maintained above 90%.





#### Pressure- Linear Flow Rate Curve - Tris

#### Monomix Mab60-Q Pressure – Linear flow rate



Column pressure drop is around 2.4 bar at 1000 cm/h linear flow rate.

The column pressure drop is around 0.5 bar under convention line flow rate range (100~200 cm/h).

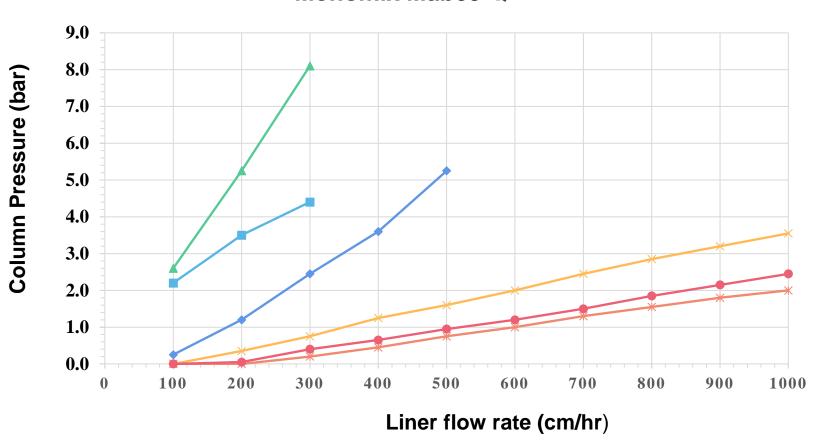
Column: Monomix Mab60-Q (10\*200 mm, CV=15.7 mL)Moble pase: 50 mmol/L **Tris** (pH8.5)





#### Pressure- Linear Flow Rate Curve - Different Buffers

#### Monomix Mab60-Q



**→** water

---2% phenylcarbinol

→20% Ethanol

→ 0.01M NaCl

→ 0.1M NaCl

-0.5M NaCl

It is recommended to reduce the linear flow rate appropriately when wash the column with using pure water, 20% ethanol, and 2% benzyl alcohol.

Column: Monomix Mab60-Q (10\*200 mm, CV=15.7 mL)

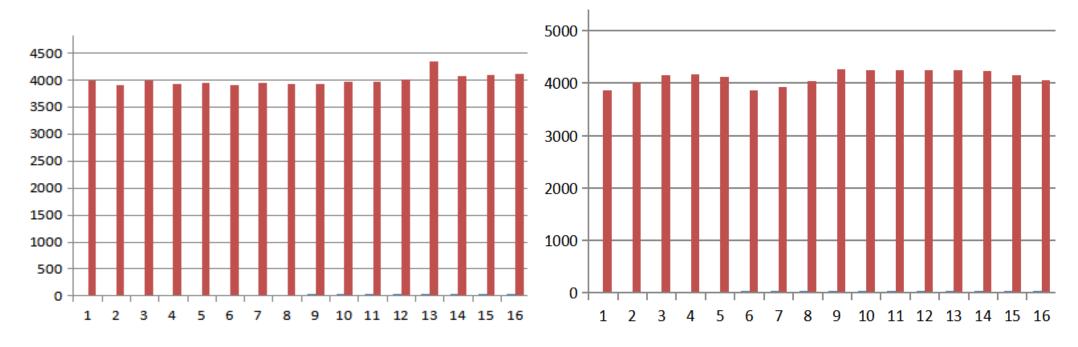




#### **BSA Protein absorption-NSB test**

#### Monomix Mab60-Q NSB Test, peak area trend

#### Other vendor's resin NSB Test, peak area trend



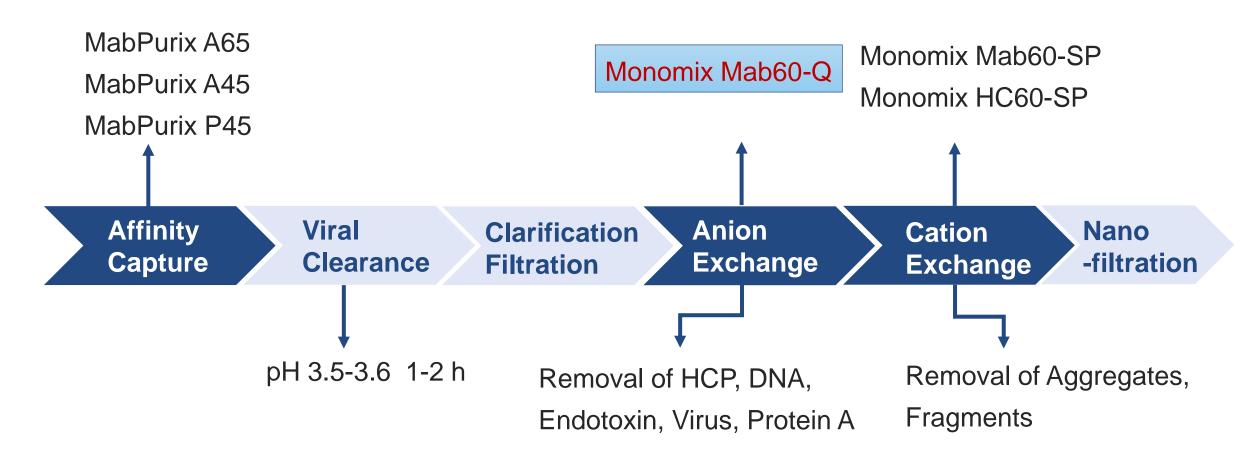
Monomix Mab60-Q nonspecific binding to BSA protein standard is low



## **Antibody Downstream Purification**



### Three Step Process





### Monomix Mab60-Q Application - BsAbs



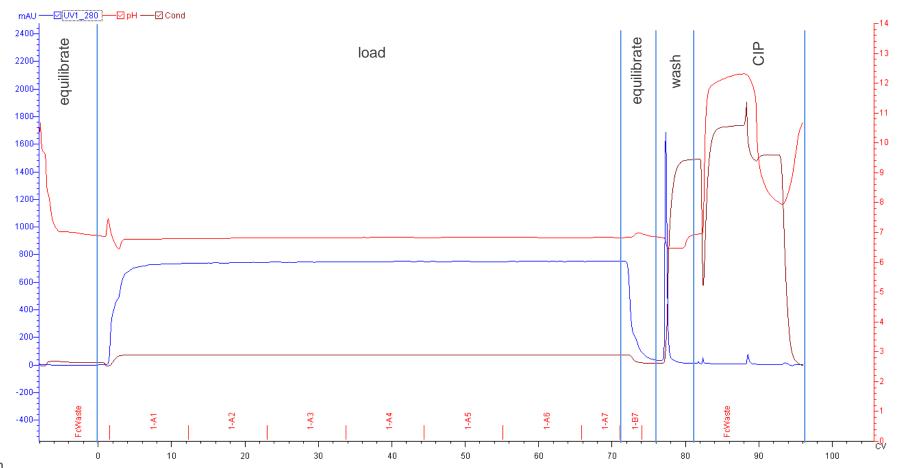
#### Bispecific Antibody HCP Residue Analysis

Column: Monomix Mab60-Q (4.2 mL prepacked column)

Mobile phase: A: 20 mM Tris-Hac, pH 7.0; B: 20 mM Tris-Hac, 1 M NaCl, pH 7.0

Flow rate: 0.84 mL/min (5 min residence time) Detector: UV 280 Column temperature: RT

Sample: bispecific antibody eluent after the affinity purification step (2.11 mg/mL, pH: 7.0, Cond: 4.32 mS/cm)



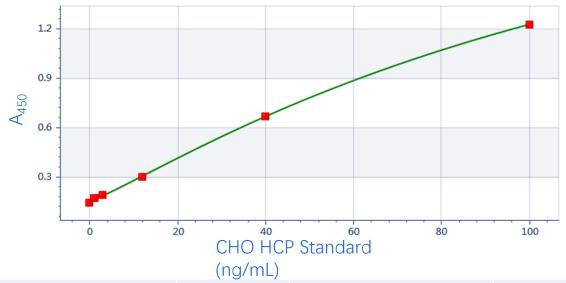


### Monomix Mab60-Q Application - BsAbs



#### Bispecific Antibody HCP Residue Analysis

CHO HCP Standard [ng/mL]	Original Signal (A <sub>450</sub> )
0	0.1442
1	0.1722
3	0.1945
12	0.3007
40	0.6707
100	1.2280



	Raw HCP [ng/mL]	Dilution factor	HCP in Sample [ng/mL]	Eluent Volume [mL]	Antibody in Eluate [mg/mL]	HCP Residue [ng/mg]
Monomix Mab60-Q	15.50	2.5	38.75	279.29	2.00	19.38

<sup>\*</sup> The HCP concentration in the crude sample is above the maximum detection range

<sup>\*</sup> The HCP concentration in the loading sample (after Protein A affinity purification and membrane filtration) was ~450 ppm.

<sup>\*\*\*</sup> The HCP concentration in eluate after Monomix Mab60-Q purification is 19.38 ppm. Thus, the HCP concentration is reduced by a factor of 23 after Monomix Mab60-Q purification.



### Monomix Mab60-Q Application - BsAbs



#### Bispecific Antibody HCP Residue Analysis - Recovery

Resir		umn ume nL]	Load [mg/mL]	Sample Volume [mL]	Elution Volume [mL]	ProAqa Excel Peak Area	ProAqa Excel Sample Peak Area	Sample Peak Area*Sample Volume	Collect sample peak areas* Elution Volume	Recovery (%)
Monor Mab60	Δ	.2	137.5*	273.6	279.29	1980.3	2077.9	568513.44	553077.987	97.28

The protein recovery rate in the bispecific antibody HCP removal experiment by using Monomix Mab60-Q is greater than 97%



## **Order Info**



Product	Particle Size	PN	Pack Size (L)	Cartridge (mL)
MabPurix P45	45 µm	270845990	0.5, 1, 5, 10, 100	4.2
MabPurix A45	45 µm	270745990	0.5, 1, 5, 10, 100	4.2
MabPurix A65	65 µm	270765990	0.5, 1, 5, 10, 100	4.2
Monomix Mab60-Q	60 µm	285060950	0.5, 1, 5, 10, 100	4.2
Monomix HC60-SP	60 µm	280660950	0.5, 1, 5, 10, 100	4.2
Monomix Mab60-SP	60 µm	284760950	0.5, 1, 5, 10, 100	4.2
Monomix MC60-HIC Butyl	60 µm	281660950	0.5, 1, 5, 10, 100	4.2
Polar MC60-HIC Phenyl	60 µm	191360800	0.5, 1, 5, 10, 100	4.2



# Thank You!

Check our website for more products <a href="https://www.sepax-tech.com">www.sepax-tech.com</a>

Affinity | IEX | Mixed Mode| Multimodal | HIC | SEC | RP

