Purcise™ Q Strong Anion Exchange Membrane Adsorber (Chromatography)

Purcise™ Q Membrane is a novel anion exchange medium that modifies specific functional groups in a crosslinked polymer coating to achieve the separation and purification of negatively charged components.

Purcise™ Q membrane adsorber (chromatography) medium features sufficiently large pore channels that allow larger biomolecules to pass through, while enabling convective mass transfer on the channel surfaces, thus facilitating rapid binding of target molecules to ligand sites. Compared to traditional column chromatography media, membrane adsorber (chromatography) media offer higher process flow rates to shorten processing times and possess higher dynamic binding capacities for biomolecules (such as plasmid DNA, enveloped viruses, host cell proteins, etc.), thereby reducing process costs.

Typical Applications

Removal of contaminants such as host DNA, viruses, host cell proteins and endotoxins from biological fluids

Capture of relatively large target molecules (e.g. recombinant proteins, plasmids, viral vectors and plasma fractions)

Purification of small molecules such as oligonucleotides, peptides

Features and Benefits

High Binding Efficiency
Membrane chromatography media have large enough pore channels to exhibit high loading at low pressure drop as well as high flow rates. Membrane chromatography media are based on the principle of convective mass transfer, which allows charged biomolecules to be bound in a single pass through the membrane, making it less dependent on retention time.

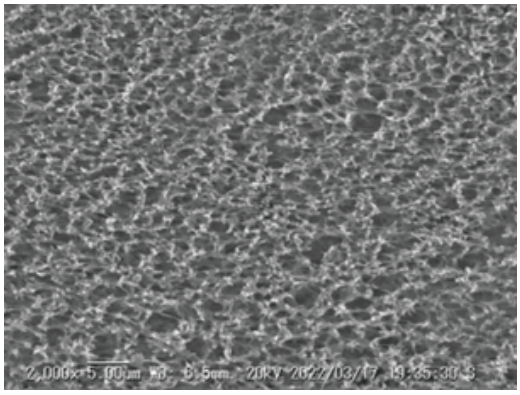
High Flow Rates
Membrane chromatography media are recommended for operating flow rates of 10 MV/min within pressure limits (9 ml/min for 0.9 ml membranes), resulting in 30 to 50 times faster productivity with membrane chromatography than with traditional packed chromatography.

Scalability and Flexibility
A full range of membrane chromatography media is available to meet the volume and performance needs of the biopharmaceutical industry, from process development to the largest scale of production. Membrane chromatography media can be single-use or cleaned and reused.

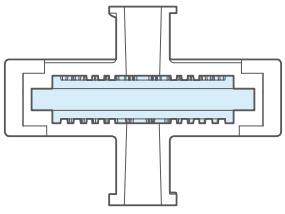
Reproducible
The full range of membrane chromatography media is manufactured to strict ISO 9000 standards to ensure reproducible processes, conformity to specifications and consistent performance.

Low Cost
Membrane chromatography media are less expensive to operate (e.g. less buffer, less time investment, etc.) and less capital intensive (e.g. no additional hardware investment required, etc.) than conventional columns that require efficient loading and cleaning programmes.

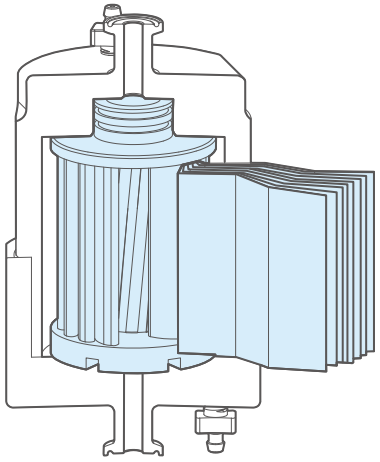
Easy to Use
The easy-to-use filter format requires only a simple connection for immediate use, eliminating the need for column loading. If the product is single-use, there is even no cleaning.



Purcise™ Q Strong Anion Exchange Membrane Adsorber utilizes proven hydrophilic PES membrane technology. The membrane offers outstanding chemical compatibility and minimal non-specific adsorption, ensuring high purity and efficient separation.



Lab trail membrane structure diagram



Pilot and production specification structure

Membrane Details

Product Series	**Purcise™ Q**
Membrane Materials	PES
Functional Group	Mixed amino group
Typical Operating Flow Rate	1-25 MV/min
Nominal Pore Size	0.7 μm
BSA Binding Capacity	>50 mg/mL
DNA Binding Capacity	>20 mg/mL
Pre-use Storage Conditions	Store at room temperature or 2~8°C
Post-use Storage Solution	0.1M NaOH

Product Specification I

Specification	CXU33	CXD32	
Lab Scale			
Volume	0.2 mL	0.45 mL	0.9 mL
Minimum standards BSA binding capacity	50 mg/ml	50 mg/ml	50 mg/ml
Membrane Configuration	Flat sheet	Flat sheet	Flat sheet
Layers	3	8	16
Connection forms	I : Female Luer; O: Similar to Male Luer	Female Luer	Female Luer
Structural material	Upper : PP Lower : PP	Upper : PP Lower : PP	Upper : PP Lower : PP
Recommended flow rate range*	0.2-5 mL/min	0.45-11.25 mL/min	0.9-22.5 mL/min
Max. operating pressure	4.0 bar	4.0 bar	4.0 bar
Typical application	Process development experiments; Scaled down laboratory tests		

Specification	CX0005	CX0010	CX0025	CX0050
Lab Scale				
Volume	5.0 mL	10.0 mL	25.0 mL	50.0 mL
Minimum standards BSA binding capacity	50 mg/ml	50 mg/ml	50 mg/ml	50 mg/ml
Membrane Configuration	Pleated	Pleated	Pleated	Pleated
Layers	8	16	8	16
Connection forms	M6 Tapered Thread Port	M6 Tapered Thread Port	TC25	TC25
Structural material	Membrane Support Layer / Drainage Structure: PP Core / Support / End Cap: PP Membrane Shell: PP Seal Ring: Red Silicon Valve: PP			
Recommended flow rate range*	5-125 mL/min	10-250 mL/min	25-625 mL/min	50-1250 mL/min
Max. operating pressure	3.0 bar	3.0 bar	3.0 bar	3.0 bar
Typical application	Process Development Experiment	Process Development Experiment	Pilot-Scale Experiment	Pilot-Scale Experiment

Product Specification II

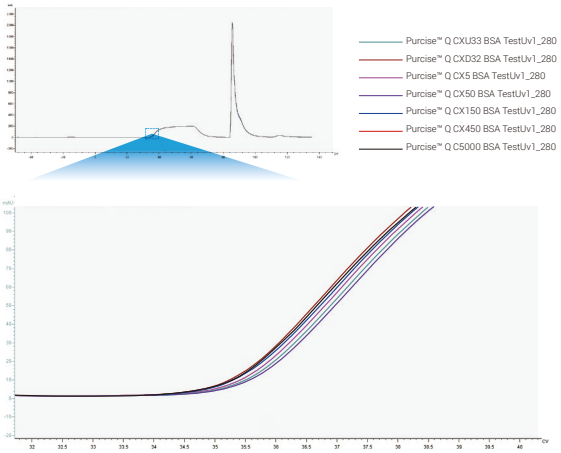
Specification	CX0075	CX0150	CX0225	CX0450
Pilot & Production Specification				
Volume	75 mL	150 mL	225 mL	450 mL
Minimum standards BSA binding capacity	50 mg/ml	50 mg/ml	50 mg/ml	50 mg/ml
Membrane Configuration	Pleated	Pleated	Pleated	Pleated
Layers	8	16	8	16
Connection forms	TC25	TC25	TC25	TC25
Structural material	Membrane Support Layer /Drainage Structure: PP Core / Support / End Cap: PP		Membrane Shell: PP Seal Ring: Red Silicon	Valve: PP
Recommended flow rate range*	0.075-1.875 L/min	0.15-3.75 L/min	0.225-5.625 L/min	0.45-11.25 L/min
Max. operating pressure	3.0 bar			

Specification	CX1000	CX2000	CX2500	CX5000
Pilot & Production Specification				
Volume	1000 mL	2000 mL	2500 mL	5000 mL
Minimum standards BSA binding capacity	50 mg/ml	50 mg/ml	50 mg/ml	50 mg/ml
Membrane Configuration	Pleated	Pleated	Pleated	Pleated
Layers	8	16	8	16
Connection forms	TC50	TC50	TC50	TC50
Structural material	Membrane Support Layer /Drainage Structure: PP Core / Support / End Cap: PP		Membrane Shell: PP Seal Ring: Red Silicon	Valve: PP
Recommended flow rate range*	1-25 L/min	2-30 L/min	2.5-62.5 L/min	5-75 L/min
Max. operating pressure	3.0 bar			

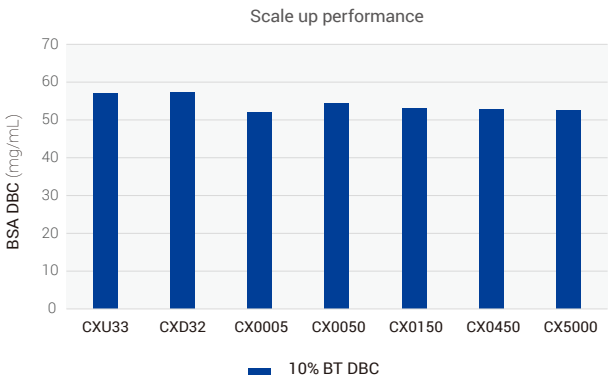
* Recommended flow rates are based on 1-25 film volumes/min. Actual process flow rates will be determined based on process requirements, maximum back pressure, and process time.

Dynamic Binding Capacity Test

BSA Binding / Elute Curve



Laboratory scale-up performance (in terms of BSA-binding capacity)



Note: 2mg/mL BSA in 25mM Tris, pH 8.0 was pumped at a flow rate of 10 MV/min through the Purcise™ Q (CXD32) membrane.

Actual Test Data for Purcise™ Q Removal of Host Protein (HCP) from Antibody Samples

Actual Test Data 1				
Samples	HCP	HMW	SEC Main Peak	LMW
Initial samples	28 ng/mg	2.07 %	97.89 %	0 %
pH 8.2 Cond.~4 mS/cm	3.5 ng/mg	1.73 %	98.26 %	0 %
pH 7.75 Cond.~4 mS/cm	4.8 ng/mg	1.65 %	98.35 %	0 %
pH 7.5 Cond.~4 mS/cm	4.3 ng/mg	1.59 %	98.41 %	0 %

Note: Data for removal of host cell proteins are from experiments with Protein A purified monoclonal antibody (mAb) Low pH incubation for anionic flow-through after deep filtration. The flow rate in the Purcise™ Q was 25 MV/min.

Actual Test Data 2				
Samples	HCP	HMW	SEC Main Peak	LMW
Initial samples	699 ppm	8.1 %	91.5 %	0.3 %
pH 6.46, Cond. 3.80 mS/cm	30 ppm	6.5 %	93.1 %*	0.3 %
pH 7.02, Cond. 3.87 mS/cm	35 ppm	3.3 %	96.4 %*	0.3 %

Note: Data for host cell protein removal were obtained from experiments with anion passage after incubation with Protein A purified monoclonal antibody (mAb) Low pH. The HCP removal test load was 1000 mg/ml (with sample limited), the polymer removal test load was 60 mg/ml, and the flow rate within Purcise™ Q was 10 MV/min.

Actual Test Data 3			
Samples	Description	Load	HCP
Initial samples	Initial samples	N/A	216 ppm
Samples 1	pH 7.5, Cond. <5mS/cm through hybrid samples	0.5 g/ml	< 9 ppm
Samples 2	pH 7.5, Cond. <5mS/cm through hybrid samples	2.0 g/ml	15 ppm
Samples 3	pH 7.5, Cond. <5mS/cm through hybrid samples	4.0 g/ml	20 ppm
Samples 4	pH 7.5, Cond. <5mS/cm through hybrid samples	4.0 g/ml	24 ppm

Note: Data for removing host cell proteins were obtained from the anion passage experiment after incubation with Protein A purified monoclonal antibody (mAb) Low pH, in which the flow rate within the Purcise™ Q was 10 MV / min

Purcise™ Q Virus Removal Test

Challenge Test Conditions

Parameter	Condition 1 - Two Parallel Groups	Condition 2 - Two Parallel Groups
pH and Conductivity	pH 7.0, Conductivity ~6 mS/cm	pH 8.0, Conductivity ~6 mS/cm
Membrane Volume	0.9 ml (Lot. CXD32EAQ16CC1P)	
Flow Rate	10 MV/min 9 ml/min	
Challenged Virus Types	MVM, X-MuLV, Reo-3, PrV	
mAb Concentration	9.42 g/L	
Load Volume	3.1 kg/L (g/ml)	
Residual HCP in Flow Through	~20 ppm	

Virus Clearance Results

Virus Type	Run 1 pH 7.0		Run 2 pH 8.0	
	Actual Spiked Level (log 10)	LRV	Actual Spiked Level (log 10)	LRV
X-MuLV	7.02	> 5.55 ± 0.20	6.86	> 5.38 ± 0.33
MVM	8.04	4.79 ± 0.14	8.06	5.80 ± 0.31
Reo-3	8.21	> 6.86 ± 0.21	8.25	5.77 ± 0.14
PrV	8.46	> 6.99 ± 0.16	8.11	> 6.63 ± 0.12

Purcise™ Q strong anion exchange membrane adsorber (chromatography) effectively removes four model viruses under different conditions, achieving LRV values >4. Compared to traditional anion exchange resin chromatography, the Purcise™ Q offers higher process flow rates and greater sample loading capacity, ensuring process performance while reducing costs and increasing efficiency. Additionally, it minimizes the initial hardware investment for companies.

Purcise™ Q Endotoxin Removal Test

Test Conditions

Conducting DOE Experiments to Study the Performance of Q Membrane in Removing Endotoxins from Formulation Buffers under Low Load Conditions

Condition	Low	High
pH	4	9
Sucrose Concentration	0 % (W/V)	15 % (W/V)
NaCl Concentration	0 mM	200 mM

Test solution spiked with endotoxin concentration: 100 EU/ml
Purcise™ Q membrane volume: 0.9 ml (configured with 16 layers)
Purcise™ Q membrane filtration spiked solution volume: 90 ml
Filtration flow rate: 9 ml/min (10 MV/min)
Collect the solution before and after Q membrane filtration, and measure the endotoxin concentration. The endotoxin removal is expressed using log reduction value (LRV).

Test Results

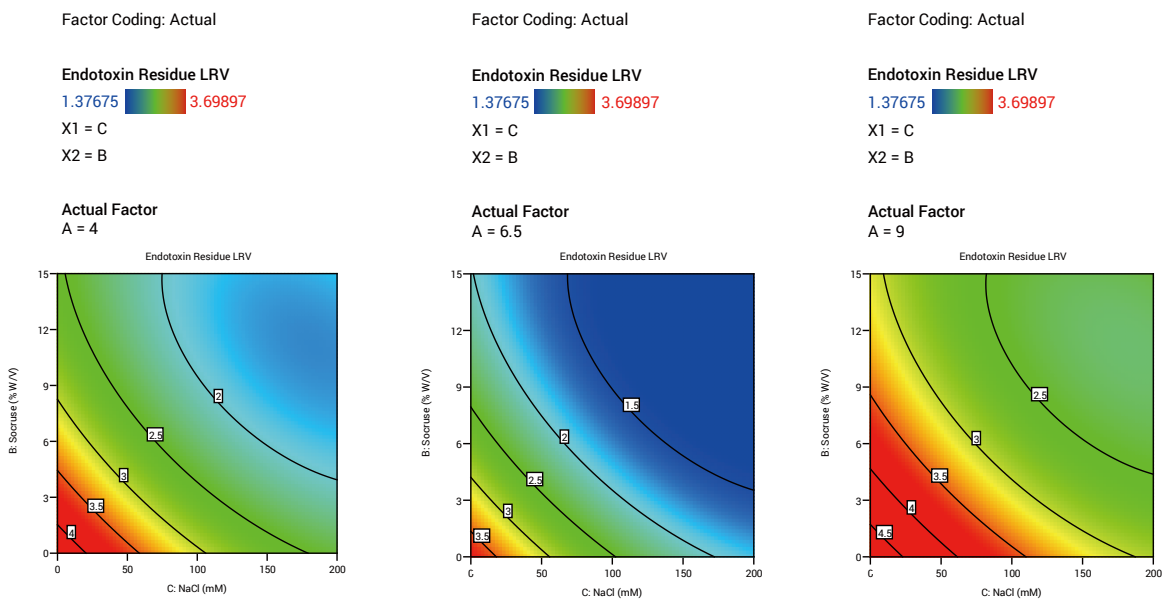
Endotoxin Clearance LRV =1.60 + 0.2675*A - 0.5826*B - 0.6498*C + 0.2937*BC + 0.8019*A^2 + 0.3434*B^2 + 0.3048*C^2, where

A: pH

B: Sucrose Concentration

C: NaCl Concentration

Response Surface Curves



At **pH 4**, the response surface curve of B: sucrose concentration and C: sodium chloride concentration.

At **pH 6.5**, the response surface curve of B: sucrose concentration and C: sodium chloride concentration.

At **pH 9**, the response surface curve of B: sucrose concentration and C: sodium chloride concentration.

Recommended Conditions for Virus Removal with Purcise™ Q:
pH: 4 ~ 9, Sucrose Concentration: 0 ~ 9%, NaCl: 0 ~ 50 mM
Purcise™ Q Endotoxin Residue LRV > 3

Ordering Information

Products No.	Description	Membrane volume	Packaging
CXU33EAQ03CP1P	Purcise™ Q Membrane Chromatography Syringe filter	0.2 ml	1/pkg
CXU33EAQ03CP4P		0.2 ml	4/pkg
CXD32EAQ08CC1P		0.45 ml	1/pkg
CXD32EAQ08CC4P		0.45 ml	4/pkg
CXD32EAQ16CC1P		0.9 ml	1/pkg
CXD32EAQ16CC4P		0.9 ml	4/pkg
CX0005EAQ08M61P	Purcise™ Q Membrane Chromatography Capsule Filter	5 ml	1/pkg
CX0010EAQ16M61P		10 ml	1/pkg
CX0025EAQ08KK1P		25 ml	1/pkg
CX0050EAQ16KK1P		50 ml	1/pkg
CX0075EAQ08KK1P		75 ml	1/pkg
CX0150EAQ16KK1P		150 ml	1/pkg
CX0225EAQ08KK1P		225 ml	1/pkg
CX0450EAQ16KK1P		450 ml	1/pkg
CX1000EAQ08SS1P		1 L	1/pkg
CX2000EAQ16SS1P		2 L	1/pkg
CX2500EAQ08SS1P		2.5 L	1/pkg
CX5000EAQ16SS1P		5 L	1/pkg
CXM6KIT	M6 Inverted Cone Fitting Accessory Kit	-	1/pkg

cobetter® filtration

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Ver. 01b

* Specifications subject to change without notice.