

# Mustang™ Q XT

## CHROMATOGRAPHY CAPSULES

### Reusable ion exchange membrane chromatography

#### Meeting process demands for scalability and economy

The use of ion exchange chromatography for purification in downstream processing is well established.

Many regulatory-approved processes make use of large process columns packed with ion exchange sorbent for effective and reliable performance. As demand intensifies for improved throughput and reduced processing costs, Mustang™ ion exchange membrane technology keeps pace, enabling process developers to harness:

- Reduced process times through use of high volumetric flow rates
- Improved process economics through increased throughput and reduced buffer consumption
- Enhanced process flexibility through use of a smaller operating footprint

Membrane capsule design and chromatography competencies have been combined to develop a range of high performance, scalable Mustang Q XT membrane chromatography capsules. These capsules are robust and easy to use, and enable users to optimize their process by reducing buffer consumption, increasing throughput and decreasing capital expenditure.

Processes benefit from:

- **High binding efficiency**  
Mustang Q XT capsules exhibit high capacities and high flow at low pressure drops, allowing binding of large charged biomolecules such as plasmids and lentiviruses in a single pass.
- **Speed**  
Membrane binding capacity is not significantly affected by flow rate. Mustang Q capsules typically operate at 10 MV/min flow rates (up to 50 L/min for XT5000), enabling membrane chromatography to process much faster than conventional chromatography sorbents.  
High flow rates enable the processing of large volumes in less than a single working shift.
- **Scalability and flexibility**  
A range of capsule sizes accommodates various volumes and capacities required in biopharmaceutical processing, from process development to full-scale manufacturing.  
Capsules can be deployed in single-use applications or can be regenerated and reused.



Fig 1. Mustang Q XT chromatography capsule range.

- **Reproducibility**  
Capsules are manufactured using the statistical process control (SPC) system to enable the process to be reproduced in a consistent manner.  
The consistency of the process enables conformance to specifications and delivers consistent process results.
- **Convenience**  
Easy-to-use capsules eliminate the need for packing protocols. In single-use applications, there are no cleaning, cleaning validation or cross-contamination issues.
- **Lower cost**  
Membrane capsules offer lower operating and capital investment costs than conventional columns that require validated packing and cleaning protocols.
- **Reduced buffer consumption**  
The small footprint requires less buffer yet maintains efficient contaminant removal performance.  
Mustang Q capsules XT5 to XT5000 are suitable for screening and optimization studies as they are made with the same construction materials and consistent void volume-to-membrane ratio, for scalable chromatographic performance. The XT5 is suited to scale-down optimization studies.

# Technical specifications

**Table 1.** Specifications of Mustang Q membrane in XT Acrodisc™ unit

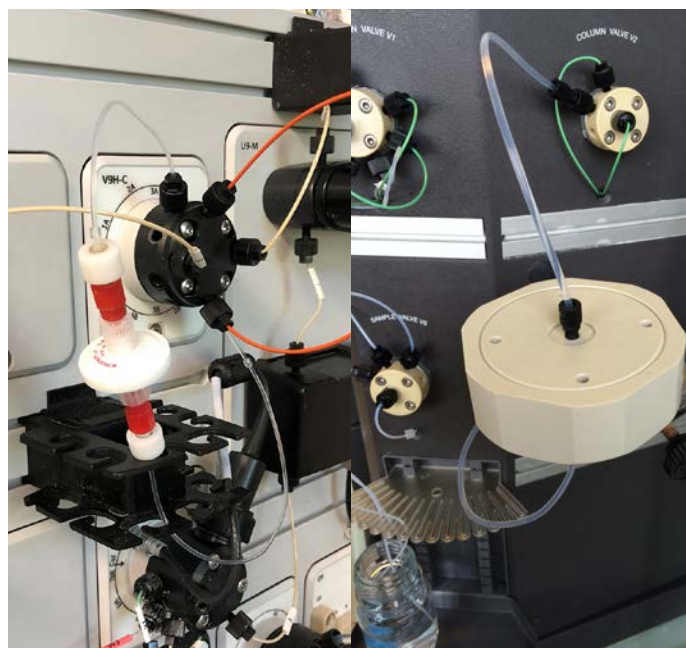
Product code (P/C)	MSTGXT25Q16
Membrane bed volume	0.86 mL
Housing	Polypropylene
Media	16-layer Mustang Q 0.8 µm membrane
Connections	Female luer-lock inlet and outlet
Maximum operating pressure	4 bar (58 psi)
Recommended connectors for chromatography workstation	Luer to ¼–28 female adaptor (Bio-Rad, product code 732-0113)



**Fig 2.** XT Acrodisc units with Mustang Q membrane.

**Table 2.** Specifications of Mustang Q XT capsules

Type of Mustang Q XT capsule	5 mL scale down (P/C XT5MSTGQPM6)	50 mL scale up (P/C XT50MSTGQP05)	140 mL pilot scale (P/C XT140MSTGQP05)	450 mL process (P/C XT450MSTGQP05)	5 L process (P/C XT5000MSTGQP1)
<b>Materials of construction</b>					
Membrane	Modified hydrophilic polyethersulfone (PES) membrane with cross-linked quaternary amine (QC release: BSA binding capacity specification 53–84 mg/mL at 80% breakthrough)				
Membrane support and drainage	Polypropylene				
Core/cage/end caps					
Maximum operating housing					
O-rings	Silicone				
Valve	Not applicable	Polypropylene	Polypropylene	Polypropylene	Polypropylene
<b>Nominal dimensions</b>					
Capsule length without protective caps	39 mm (1.5 in.)	132 mm (5.20 in.)	190 mm (7.48 in.)	339 mm (13.35 in.)	605 mm (23.8 in.)
Maximum diameter of capsule body	97 mm (3.8 in.)	107 mm (4.21 in.)	107 mm (4.21 in.)	107 mm (4.21 in.)	270 mm (10.6 in.)
Weight dry	187 g (6.6 oz.)	555 g (1.22 lb.)	768 g (1.5 lb.)	1436 g (3.16 lb.)	10.3 kg (22.7 lb.)
Weight in use (filled)	195 g (6.88 oz.)	653 g (1.44 lb.)	1009 g (2.0 lb.)	2207 g (4.86 lb.)	19.6 kg (43.2 lb.)
Connectors	Female M6 threads	0.5 in. sanitary flange	0.5 in. sanitary flange	0.5 in. sanitary flange	1.5 in. sanitary flange



**Fig 3.** Preliminary evaluation of membrane performances executed with Acrodisc units (0.86 mL – left) and scaled up with Mustang XT5 capsule (5 mL – right).

# Operating characteristics

**Table 3.** Operating characteristics of Mustang Q XT capsules <sup>(1)</sup>

Type of Mustang Q XT capsule	5 mL scale down (P/C XT5MSTGQPM6)	50 mL scale up (P/C XT50MSTGQP05)	140 mL pilot scale (P/C XT140MSTGQP05)	450 mL process (P/C XT450MSTGQP05)	5 L process (P/C XT5000MSTGQP1)
Maximum operating temperature	38°C	38°C	38°C	38°C	38°C
Maximum operating pressure	5 bar (72.5 psi) at 38°C	3 bar (43.5 psi) at 38°C	3 bar (43.5 psi) at 38°C	3 bar (43.5 psi) at 38°C	3 bar (43.5 psi) at 38°C
Storage conditions	0.1 M NaOH + 1 M NaCl	0.1 M NaOH + 1 M NaCl	0.1 M NaOH + 1 M NaCl	0.1 M NaOH + 1 M NaCl	0.1 M NaOH + 1 M NaCl

<sup>(1)</sup> With fully compatible fluids that do not soften, swell or adversely affect the capsule or its materials of construction.

## Advanced Mustang membrane technology

Mustang membrane is a polyethersulfone (PES)-based membrane with a 0.8 µm nominal pore size and a surface coating of an irreversibly cross-linked polymer containing quaternary amine groups. Mustang membrane chromatography allows rapid and direct access to the membrane binding sites for large biomolecules (nucleic acids and proteins) and virus particles by direct fluid convection.



**Fig 4.** All sizes use 16 layers of Mustang Q membrane in Ultipleat® structure.

## Capsule design

Mustang Q XT capsules are available in multiple scalable sizes from 5 mL to 5 L volumes and are constructed with 16 layers of Mustang Q membrane for consistent performance. Set-up is simple, and each capsule is integrity tested before shipment for additional quality assurance. If required, process capacities can be increased by linking units in parallel or series.

The durable polypropylene housings have been designed to reduce upstream and downstream hold-up volume, enhancing chromatographic performance (Table 4). The housings provide the chemical stability needed for cleaning, reuse and long-term storage, allowing sanitization and storage in 0.1 M NaOH / 1 M NaCl for up to 12 months.

## Seamless scalability

Scalability is enabled via using 16 layers of membrane across all product sizes. By maintaining a constant membrane bed height, chromatographic performance is maintained across the product range. Scalable Mustang Q XT products meet processing requirements in a range of volumes:

- Screening and pre-clinical: Mustang Q membrane in XT Acrodisc unit (0.86 mL) and Mustang Q XT5 capsule (5 mL)
- Laboratory scale process development work and small-scale clinical manufacturing runs: Mustang Q XT50 (50 mL) and XT140 (140 mL) capsules
- Process scale clinical manufacturing: Mustang Q XT450 (450 mL) and XT5000 (5 L) process scale capsules

**Table 4.** Hold-up volume comparison across sizes

Mustang Q capsule type	Bed volume (mL) (A)	Void volume (mL) (B)	Ratio A/B	EFSA <sup>(3)</sup> (cm²)
XT5	5	8	1.60	22
XT50	50	98	1.97	236
XT140	140	260	1.86	660
XT450	450	770	1.71	2121
XT5000	5000	9200	1.84	22 000

<sup>(2)</sup> Total liquid capsule fill volume including pores (mL).

<sup>(3)</sup> Effective functional surface area.

**Table 5.** Typical BSA dynamic binding capacity at 10 MV/min, demonstrating linear scalability – samples selected at random

Mustang Q capsule	Membrane volume (mL)	Breakthrough (mg/mL)	Pressure drop (bar [psi]) <sup>(4)</sup>
XT Acrodisc unit	0.86	83 ± 6	0.35 (5)
XT5	5	85 ± 5	0.68 (10)
XT50	50	82 ± 15	0.41 (6)
XT140	140	69 ± 10	0.48 (7)
XT450	450	87 ± 3	0.55 (8)
XT5000	5000	75 ± 3	0.62 (9)

<sup>(4)</sup> Measured at 10 MV/min with Tris buffer.

## Applications

Mustang Q XT capsules with the same membrane technology and smaller membrane volumes are used in a wide range of approved processes and clinical trials for applications, such as:

- Capture of lentiviruses
- Plasmid purification
- Adeno-associated virus (AAV) and adenoviruses purification
- Purification of large protein
- Monoclonal antibody polishing

In capture applications where the target molecule is relatively large, Mustang membrane exhibits improved capacities and recoveries and higher flow rates compared to packed bed sorbents. Each Mustang Q XT capsule is engineered with a uniform flow path and very low total volume-to-membrane -volume ratio, enabling good resolution with high yields and low elution volumes.



**Fig 5.** Mustang Q XT140 capsule and Mustang Q XT5 capsule.

## Application examples

### Capture and recovery of plasmid DNA (7 kb) from *E. coli* lysate

**Table 6.** Efficient recovery of plasmid DNA from clarified lysate with Mustang Q XT140 capsule

Mustang XT140 fraction (7 kb)	Total volume (L)	pDNA (g/L)	Endotoxin (EU/mg)	Total pDNA (g)	Yield (%)
Load	36.80	0.10	<sup>(5)</sup>	3.68	–
Mustang Q XT pDNA eluate	3.33	0.89	204	2.96	80

Loading conductivity 89.6 mS/cm following alkaline lysis loaded in two cycles at 10 MV/min flow rate.

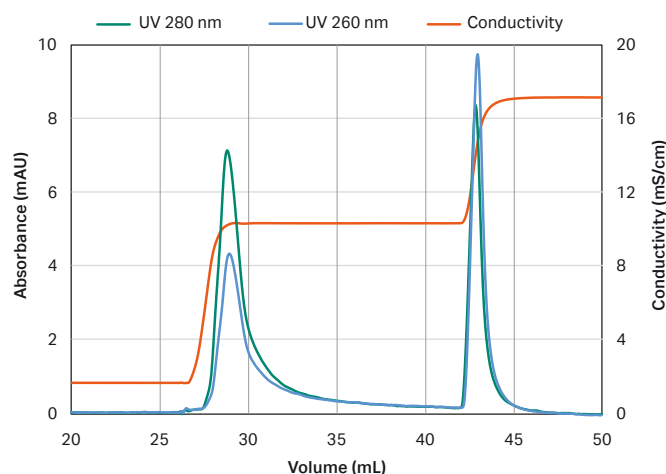
<sup>(5)</sup> Not measured, but refer to typical endotoxin levels from *E. coli* lysate  $2.1 \times 10^6$

(S. Zhang, A. Krivosheyeva and S. Nochumson. Biotechnol. Appl. Biochem. [2003] 37, 245-249.)

Data courtesy of A. Carnes, Nature Technology, Wilbio Conference, November 2008.

## Viral vector purification

Mustang Q XT membrane provides efficient reduction of empty capsids and enrichment of full capsids in a single bind and two-step elution method. The eluate of the first elution step consists of predominantly empty capsids. The eluate of the second elution step consists of enriched full capsids.



**Fig 6.** Mustang Q XT Acrodisc unit (0.86 mL) two-step elution method with AA5 capsids; (left peak) predominantly empty capsids, (right peak) enriched full capsid peak.

## High standards of quality

- Manufactured to high quality assurance standards in accordance with ISO 9000.
- Membrane lots tested for dynamic protein and DNA binding capacity.
- Identified by lot number together with a unique serial number for traceability of manufacturing history, satisfying QC/QA requirements.
- Supplied with certificate of analysis to confirm quality standards.
- Meets USP biological reactivity tests *in vivo* in accordance with requirements for USP Class VI-50°C.

## Ordering information

Product	Packaging	Product code
Mustang Q XT 5 L membrane volume for clinical manufacturing	1/pkg	XT5000MSTGQP1
Mustang Q XT 450 mL membrane volume for clinical manufacturing		XT450MSTGQP05
Mustang Q XT 140 mL membrane volume for pilot scale process development		XT140MSTGQP05
Mustang Q XT 50 mL membrane volume for pilot scale process development		XT50MSTGQP05
Mustang Q XT 5 mL membrane volume for scale-down process development <sup>(6)</sup>		XT5MSTGQPM6
Mustang Q membrane in XT Acrodisc unit (0.86 mL)	4/pkg	MSTGXT25Q16

<sup>(6)</sup> The capsule inlet and outlet have female M6 threads and include connectors and tubing.

Mustang XT5000 capsules can be connected to increase total available process volume up to three capsules using the Mustang XT5000 stand.

Product	Packaging	Product code
Stand base unit (lower section)	1/pkg	XT5000B100
Top (upper) section		XT5000T100
Lifting handle		XT5000H100

Please contact us for more information on the XT5000 capsules stand, and other cartridges and configurations.



**Fig 7.** Mustang Q XT5000 capsule.

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