Mustang™ Q

CHROMATOGRAPHY CAPSULES

High-throughput single-use capsules for process scale anion exchange chromatography

Mustang™ Q single-use products are designed to capture negatively charged biomolecules in downstream bioprocessing by anion exchange. These products will be used either for the initial capture of the target biomolecule in a purification process or for the removal of negatively charged contaminants in subsequent purification steps.

Mustang Q membrane is an anion exchange support with pendant quaternary amine functional groups in a cross-linked polymeric coating. The 0.8 µm pores in Mustang Q membranes are large enough to allow large biomolecules to access all the binding sites by direct fluid convection. This produces a very high dynamic capacity for very high molecular weight molecules (e.g., DNA, plasmid), or even particles as large as viruses. This is in contrast to conventional chromatographic beads with diffusive pores that typically have lower throughputs and dynamic binding capacities.

Combining this high-capacity Q membrane with a pleated design has resulted in the Mustang Q single-use capsule filters. Each Mustang Q element contains 16 layers of pleated membrane that will bind negatively charged biomolecules. These units are specifically designed to be single use to eliminate cleaning and cleaning validation. They are available in capsule or cartridge format to accommodate the entire range of volumes used in the biopharmaceutical processes. The 16-layer construction has been held constant from the laboratory product (0.35 mL) to the industrial scale. The ease of linear scale-up enables a shortened development time.

DNA removal efficiency

Mustang Q units will typically reduce the DNA level in a solution of sonicated calf thymus DNA from 10 µg/mL to less than 10 pg/mL in one pass. This is a removal efficiency of 6 logs. The presence of host cell protein or other contaminants, and the flow rates used, may influence test sensitivity, efficiency of binding and capacity. Performance capability in a specific solution must be determined and validated by the user. For more information, contact us.

Fig 1. The range of Mustang Q single-use capsule filters.

Features and benefits

- Binding efficiency – negatively charged biomolecules are readily bound in a single pass
- Speed – high flow rates enable the processing of large volumes in less than one shift
- Scalability – a range of sizes accommodate different volumes and capacities needed in biopharmaceutical processing
- Convenience – ready to use and autoclavable
- Flexibility – available in capsule or cartridge format
- Cost – lower operating costs and capital investment compared to conventional columns that need validated packing and cleaning

High quality standards

- Manufactured to high quality assurance standards in accordance with BS EN ISO9002 1997
- Membrane lots tested for dynamic protein binding capacity, and peak position using standard proteins
- Identified by a lot number and a specific serial number for traceability of manufacturing history, satisfying QC/QA requirements
- Supplied with certificate of analysis to confirm quality and quality control
- Meets USP biological reactivity tests *in vivo* in accordance with USP class VI 50°C and all materials listed in the drug master file submitted to the FDA

Comprehensive validation

- Extensive validation to ensure consistent and reliable performance
- Comprehensive validation guide available on request

Technical specifications

Material of construction

	Novasip™ capsule CLxMSTGQP1	Kleenpak™ Nova capsule NPxMSTGQP1
Membrane	Modified hydrophilic polyethersulfone	Modified hydrophilic polyethersulfone
Membrane support and drainage layer assembly	Polypropylene	Polypropylene
Endcaps, core and cage	Polypropylene	Polypropylene
Housing bowl	Polyetherimide	Polypropylene
Housing head	Polyetherimide with TiO_2	Polypropylene with TiO_2
O-rings	Silicone elastomer	Silicone elastomer

Note: For CLxMSTQP1, x = M05 for a unit with a bed volume of 10 mL, 3 for a unit with a bed volume of 60 mL. For NPxMSTGQP1, x = 6 for a unit with a bed volume of 260 mL, 7 for a unit with a bed volume of 520 mL, 8 for a unit with a bed volume of 780 mL.

Capsules operating characteristics [1]

Maximum operating pressure	3.0 bar (43.5 psi) at 40°C (104°F)
Maximum differential pressure	3.0 bar (43.5 psi) at 40°C (104°F)
Maximum sanitization conditions	1 M NaOH for 30 min for one cycle only
Maximum autoclave conditions	121°C (250°F) for 30 min for one cycle only

[1] With fully compatible fluids that do not soften, swell or adversely affect the capsule or its materials of construction
1 bar = 100 kPa

Available sizes and typical dynamic binding capacity

Bed volume (mL)	Typical BSA binding capacity (mg)	Flow rate (L/min/bar Delta P) [2]	Product code
0.35	17	6.400 mL/min (0.430 mL/min/psi)	MSTG18Q16
10	500	0.245 (17 mL/min/psi)	CLM05MQTGSP1
60	3000	1.250 (86 mL/min/psi)	CL3MSTGQP1
260	13 000	3.900 (269 mL/min/psi)	NP6MSTGQP1/ AB1MSTGQ7PH4
520	26 000	7.800 (538 mL/min/psi)	NP7MSTGQP1/ AB2MSTGQ7PH4
780	39 000	11.700 (807 mL/min/psi)	NP8MSTGQP1/ AB3MSTGQ7PH4

[2] For liquid of 1 cP. For other liquids, divide the flow rate by the viscosity expressed in cP.

DNA breakthrough curves on Mustang Q capsules

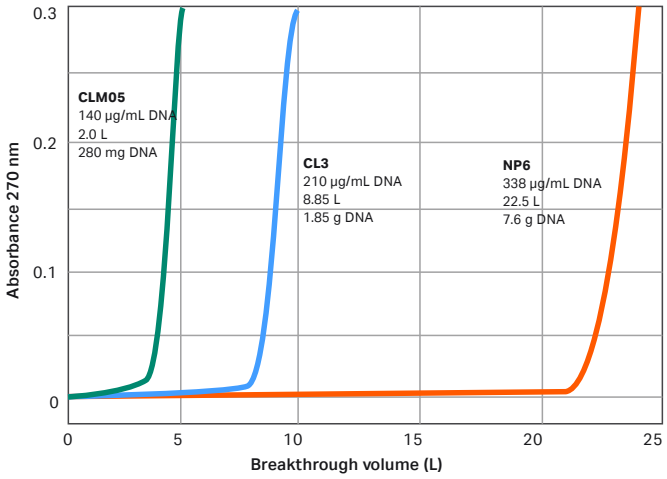

Fig 2. DNA breakthrough curves on Mustang Q capsules.

The DNA breakthrough curves above demonstrate the high breakthrough capacity of Mustang Q capsules. After preconditioning and equilibration with 25 mM Tris-HCl pH 8.0, a solution of 140 µg/mL, 210 µg/mL and 338 µg/mL of herring sperm DNA in 25 mM Tris-HCl pH 8.0 was pumped respectively through the 10 mL, 60 mL and 260 mL capsules at a flow rate of 10-20 CV/min. The absorbance at 260 nm was continuously monitored downstream of the capsule.

Scaling down unit characteristics

Materials of Construction	
Membrane	Modified hydrophilic polyethersulfone
Housing	316L stainless steel
Support frit	316B stainless steel
Housing clamp	300 series stainless steel housing
O-rings	Silicone elastomer
Nominal Dimensions	
Coin device	18 mm outer diameter
Housing	51 mm height
Fittings	M6 male to 1/16 in. OD tubing and M6 male to luer lock female fittings
Operating Characteristics	
Maximum temperature	40°C (104°F)
Maximum differential pressure	17 bar (247 psi)

Nominal dimensions for capsules

Capsule type	CLM05MSTGEP1	CL3MSTGEP1	NP6MPSTGEP1	NP7MSTGEP1	NP8MSTGEP1
Maximum diameter including valves	123 mm (4.8 in.)	123 mm (4.8 in.)	154 mm (6.1 in.)	154 mm (6.1 in.)	154 mm (6.1 in.)
Length with 38 mm (1½ in.) sanitary flange	84 mm (3.3 in.)	157 mm (6.2 in.)	333 mm (13.1 in.)	581 mm (22.9 in.)	831 mm (32.7 in.)
Bed volume (mL)	10	60	260	520	780

Ordering information

Product	Packaging	Product code
Mustang Q coin	10/box	MSTG18Q16
Stainless steel coin housing assembly	1/box	MSTG18H16
Mustang coin housing frits	2 frits/box	MSTG18H16F
Mustang coin housing gaskets	2 gaskets/box	MSTG18H16G
Mustang Q capsule, 10 mL, connections 1 to 1½ in. compatible sanitary connection	1/box	CLM05MSTGQP1
Mustang Q capsule, 60 mL, connections 1 to 1½ in. compatible sanitary connection	1/box	CL3MSTGQP1
Mustang Q capsule, 260 mL, connections 1 to 1½ in. compatible sanitary connection	1/box	NP6MSTGQP1
Mustang Q capsule, 520 mL, connections 1 to 1½ in. compatible sanitary connection	1/box	NP7MSTGQP1
Mustang Q capsule, 780 mL, connections 1 to 1½ in. compatible sanitary connection	1/box	NP8MSTGQP1
Mustang Q cartridge, 260 mL, code 7	1/box	AB1MSTGQ7PH4
Mustang Q cartridge, 520 mL, code 7	1/box	AB2MSTGQ7PH4
Mustang Q cartridge, 780 mL, code 7	1/box	AB3MSTGQ7PH4

For more information, contact us.

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