Rev. Date: 08-Jan-2011





Mustang® Chromatography Capsules and Cartridges

Description

Combining high-capacity, ion-exchange Mustang membranes with a unique 16-layer open-pleat design results in a high-flow rate, high-capacity, single-use, versatile range of pleated products that can be used for a wide range of applications.

This 16-layer construction is held constant from the laboratory-scale <u>Mustang Coin Unit</u> to the largest industrial process-scale capsule, ensuring constant <u>chromatography</u> bed depth in all formats. Mustang E capsules use three layers of a standard pleat format membrane to remove endotoxin from process feedstreams. The three-layer construction is held constant from the Mustang E Acrodisc® format to the largest industrial process scale capsule.

The ease of <u>linear scale-up</u> ensures a shortened process development time by significantly reducing the reoptimization required between scale-up steps. These units are specifically designed for single-use. This eliminates cleaning and the costs associated with cleaning validation. Mustang capsules are fully self-contained units that connect directly into a system using 18 mm (1.5 in.) sanitary flange connectors. Mustang cartridges require the use of a Code 7 housing which requires cleaning and reassembly after each use.

Mustang Q Membrane

Mustang Q membrane is an anion-exchange support with pendant quaternary amine functional groups in a cross-linked polymeric coating on a 0.8 micron pore-size membrane. This gives high dynamic capacities for high molecular weight products such as DNA, plasmids or even particles as large as viruses.

Mustang S Membrane

Mustang S membrane is a cation-exchange support with pendant sulfonic functional groups in a cross-linked polymeric coating on a 0.8 micron pore-size membrane. This gives high dynamic capacities for high molecular weight products such as IgG, Factor VIII and some viruses.

Mustang E Membrane

Mustang E membrane is a highly cross-linked quaternized amine charge polymer coating on a 0.2 micron pore size membrane. This gives very high dynamic capacities, under selected conditions for the removal of endotoxin from process feedstreams, buffers and water.

Features and Benefits

- Binding Efficiency: charged biomolecules are readily bound in a single pass
- Speed: high-flow rates enable the processing of large volumes in less than a single working shift.
 Mustang units typically operate at flow rates between 10 to 40 membrane volumes per minute, making them much faster than conventional columns which typically operate at 0.5 column volumes per minute
- Scalability: full range of sizes accommodates the different volumes and capacities required in biopharmaceutical processing

- Convenience: ready to use, autoclavable and disposable to eliminate potential packing, cleaning, validation and cross-contamination issues
- Flexible: 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 ISO 9000
- Membrane lots tested for dynamic protein binding capacity, and peak position using standard proteins
- Identified by lot number and unique serial number for complete traceability of manufacturing history, satisfying stringent QC/QA requirements
- Supplied with Certificate of Analysis to confirm quality control
- Meets USP Biological reactivity tests in vivo in accordance with USP Class VI 50 °C and all materials listed in Drug Master File submitted to the FDA

Comprehensive Validation

- Extensive validation to ensure consistent and reliable performance
- A comprehensive validation guide is available for each of the membrane chemistries on request

Products in this datasheet may be covered by one or more patents including : EP 1 189 685 US 6,849,185 US 7,189,322

Specifications

Mustang Capsules

Materials of Construction

Item	CLxMSTG*P1	NPxMSTG*P1
Membrane	Modified hydrophilic polyethersulfone	Modified hydrophilic polyethersulfone
Membrane Support and Drainage Layer Assembly	Polypropylene	Polypropylene
Core and Cage	Polypropylene	Polypropylene
Endcaps and Adapters	Polyester	Polyester
Housing Bowl	Polyetherimide	Polypropylene
Housing Head	Polyetherimide with TiO ₂	Polypropylene with TiO ₂
O-rings	Silicone elastomer	Silicone elastomer

Note:

For CLxMST*P1, x =

M05 for a Q, S or E unit with a bed volume of 10 mL

3 for a Q or S unit with a bed volume of 60 mL or an E unit with a bed volume of 40 mL

For NPxMSTG*P1, x =

6 for a Q or S unit with a bed volume of 260 mL or an E unit with a bed volume of 160 mL 7 for a Q or S unit with a bed volume of 520 mL or an E unit with a bed volume of 320 mL 8 for a Q or S unit with a bed volume of 780 mL or an E unit with a bed volume of 480 mL

Q for a unit with Q (quaternary amine) chemistry membrane S for a unit with S (sulfonic acid) chemistry membrane

E for a unit with E (polyethyleneimine) chemistry membrane

Nominal Dimensions

 Capsule Type
 CLM05MSTG*P1
 CL3MSTG*P1
 NP6MPSTG*P1
 NP7MSTG*P1
 NP8MSTG*P1

 Maximum Diameter
 123 mm (4.8 in.)
 123 mm (4.8
 154 mm (6.1 in.)
 154 mm (6.1
 154 mm (6.1

(inc. Valves)		in.)		in.)	in.)
Length with Sanitary Flange Fittings	84 mm (3.3 in.)	157 mm (6.2 in.)	335 mm (13.2 in.)	581 mm (22. 9 in.)	831 mm (32.7 in.)
Bed Volume	10 mL	Q and S = 60 mL E = 40 mL	Q and S = 260 mL E = 160 mL	Q and S = 520 mL E = 320 mL	Q and S = 780 mL E = 480 mL

^{*} Q for a unit with Q (quaternary amine) chemistry membrane; S for a unit with S (sulfonic acid) chemistry membrane; E for a unit with E (polyethyleneimine) chemistry membrane

Operating Characteristics¹

Maximum Operating Pressure; Maximum Differential Pressure 4.1 bar (59.5 psi) at 38 ℃

Maximum Sanitization Conditions

1 N NaOH for 30 minutes for one cycle only
Maximum Autoclave Conditions

1 N NaOH for 30 minutes for one cycle only

Typical Binding Characteristics

Chemistry	Molecule	MW or Size	CLM05	CL3	NP6	NP7	NP8
Q	BSA	65 kD	0.5 - 0.6 g	3.0 - 3.6 g	13 – 16 g	26 – 31 g	39 – 47 g
Q	Thyroglobulin	650 kD	0.3 g	1.8 g	7.8 g	15.6 g	23.4 g
Q	DNA	-	0.20 - 0.25 g	1.2 – 1.5 g	5.2 – 6.5 g	10.4 – 13.0 g	15.6 – 19.5 g
Q	Plasmid DNA	4.5 kb plasmid	0.15 g	0.9 g	3.9 g	7.8 g	11.7 g
Q	Plasmid DNA	12 kb plasmid	0.15 g	0.9 g	3.9 g	7.8 g	11.7 g
Q	Adenovirus	70 – 90 nm	5 x 10 ¹³ viral particles	3 x 10 ¹⁴ viral particles	1.3 x 10 ¹⁵ viral particles	2.6 x 10 ¹⁵ viral particles	3.9 x 10 ¹⁵ viral particles
S	Lysozyme	14.3 kD	0.45 - 0.50 g	2.7 – 3.0 g	11.7 – 13.0 g	23.4 – 26.0 g	35.1 – 39.0 g
S	Human IgG	160 kD	0.2 g	1.2 g	5.2 g	10.4 g	15.6 g
E	Endotoxin Units		4 x 10 ⁷ EU/capsule	1.6 x 10 ⁸ EU/capsule	6.4 x 10 ⁸ EU/capsule	1.28 x 10 ⁹ EU/capsule	1.92 x 10 ⁹ EU/capsule

Mustang Cartridges

Materials of Construction

Item Membrane Membrane Support and Drainage Layer Assembly Core and Cage Endcaps, Adapters and Bomb Fins O-rings

ABxMSTG*7PH4

Modified hydrophilic polyethersulfone Polypropylene Polypropylene Polyester Silicone elastomer

Operating Characteristics²

Maximum Operating Pressure 3 bar (43.5 psi) at 38 $^{\circ}$ C Maximum Differential Pressure 3 bar (43.5 psi) at 38 $^{\circ}$ C

Maximum Sanitization Conditions Conditions 1 N NaOH for 30 minutes for one cycle only

¹ With fully compatible fluids that do not soften, swell or adversely affect the capsule or its materials of construction

x = 1 for a 254mm (10 in.) Q or S unit with a bed volume of 260 mL 2 for a 508 mm (20 in.) Q or S unit with a bed volume of 520 mL 3 for a 762 mm (30 in.) Q or S unit with a bed volume of 780 mL * = Q for a unit with Q (quaternary amine) chemistry membrane S for a unit with S (sulfonic acid) chemistry membrane

Nominal Dimensions

Cartridge Type	Diameter	Length	Bed Volume
AB1MSTG*7PH4	70 mm (2.75 in.)	254 mm (10 in.)	260 mL
AB2MSTG*7PH4	70 mm (2.75 in.)	508 mm (20 in.)	520 mL
AB3MSTG*7PH4	70mm (2.75 in.)	762 mm (30 in.)	780 mL

^{* =} Q for a cartridge with Q (quaternary amine) chemistry membrane; S for a cartridge with S (sulfonic acid) chemistry membrane

Typical Binding Characteristics

Chemistry	Molecule	MW or Size	AB1	AB2	AB3
Q	BSA	65 kD	13 – 16 g	26 – 31 g	39 – 47 g
Q	Thyroglobulin	650 kD	7.8 g	15.6 g	23.4 g
Q	DNA	-	5.2 – 6.5 g	10.4 – 13.0 g	15.6 – 19.5 g
Q	Plasmid DNA	4.5 kb plasmid	3.9 g	7.8 g	11.7 g
Q	Plasmid DNA	12 kb plasmid	3.9 g	7.8 g	11.7 g
Q	Adenovirus	70 – 90 nm	1.3 x 10 ¹⁵ viral particles	2.6 x 10 ¹⁵ viral particles	3.9 x 10 ¹⁵ viral particles
S	Lysozyme	14.3 kD	11.7 – 13.0 g	23.4 – 26.0 g	35.1 – 39.0 g
S	Human IgG	160 kD	5.2 g	10.4 g	15.6 g

Ordering Information

Mustang Capsules

Chemistry	/ Bed Volume	Pack Quantity	Part Number	Description
Q	10 mL	1	CLM05MSTGQP1	38 mm (1.5 in.) sanitary connectors, in-line capsule
Q	60 mL	1	CL3MSTGQP1	38 mm (1.5 in.) sanitary connectors, in-line capsule
Q	260 mL	1	NP6MSTGQP1	38 mm (1.5 in.) sanitary connectors, in-line capsule
Q	260 mL	1	NT6MSTGQP1	38 mm (1.5 in.) sanitary connectors, T-style capsule
Q	520 mL	1	NP7MSTGQP1	38 mm (1.5 in.) sanitary connectors, in-line capsule
Q	520 mL	1	NT7MSTGQP1	38 mm (1.5 in.) sanitary connectors, T-style capsule
Q	780 mL	1	NP8MSTGQP1	38 mm (1.5 in.) sanitary connectors, in-line capsule
S	10 mL	1	CLM05MSTGSP1	38 mm (1.5 in.) sanitary connectors, in-line capsule
S	60 mL	1	CL3MSTGSP1	38 mm (1.5 in.) sanitary connectors, in-line capsule
S	260 mL	1	NP6MSTGSP1	38 mm (1.5 in.) sanitary connectors, in-line capsule
S	520 mL	1	NP7MSTGSP1	38 mm (1.5 in.) sanitary connectors, in-line capsule
S	780 mL	1	NP8MSTGSP1	38 mm (1.5 in.) sanitary connectors, in-line capsule

² With fully compatible fluids that do not soften, swell or adversely affect the capsule or its materials of construction

Е	10 mL	1	CLM05MSTGEP1	38 mm (1.5 in.) sanitary connectors, in-line capsule
E	40 mL	1	CL3MSTGEP1	38 mm (1.5 in.) sanitary connectors, in-line capsule
E	160 mL	1	NP6MSTGEP1	38 mm (1.5 in.) sanitary connectors, in-line capsule
E	320 mL	1	NP7MSTGEP1	38 mm (1.5 in.) sanitary connectors, in-line capsule
Е	480 mL	1	NP8MSTGEP1	38 mm (1.5 in.) sanitary connectors, in-line capsule

Mustang Cartridges

Chemistry	/ Bed Volume	Pack Quantity	Part Number	Description
Q	260 mL	1	AB1MSTGQ7PH4	254 mm (10 in.) cartridge element with Code 7 adapter
Q	520 mL	1	AB2MSTGQ7PH4	508 mm (20 in.) cartridge element with Code 7 adapter
Q	780 mL	1	AB3MSTGQ7PH4	762 mm (30 in.) cartridge element with Code 7 adapter
S	260 mL	1	AB1MSTGS7PH4	254 mm (10 in.) cartridge element with Code 7 adapter
S	520 mL	1	AB2MSTGS7PH4	508 mm (20 in.) cartridge element with Code 7 adapter
S	780 mL	1	AB3MSTGS7PH4	762 mm (30 in.) cartridge element with Code 7 adapter

Contact Information

© Copyright Pall Corporation

Visit us on the Web at www.pall.com

This information is accurate as of the revision date indicated.