

# 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 can 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.

We have combined this high-capacity Q membrane with a pleated design to form our Mustang Q single-use capsule filters. Each Mustang Q element contains 16 layers of pleated membrane that will bind negatively charged biomolecules, with a single-use composition designed 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 (0.86 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. Our range of Mustang Q single-use capsule filters.

### DNA removal efficiency

- **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 ISO9001.
- 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

### Materials of construction

|  | <b>Novasip™ capsule<br/>CLxMSTGQP1</b> | <b>Kleenpak™<br/>Nova capsule<br/>NPxMSTGQP1</b> |
|--|--|--|
| Membrane                                     | Modified hydrophilic polyethersulfone  | Modified hydrophilic polyethersulfone            |
| Membrane support and drainage layer assembly | Polypropylene                          | Polypropylene                                    |
| Endcaps                                      | Polybutylene terephthalate             | Polybutylene terephthalate                       |
| Core and cage                                | Polypropylene                          | Polypropylene                                    |
| Housing bowl                                 | Polyetherimide                         | Polypropylene                                    |
| Housing head                                 | Polyetherimide with TiO <sub>2</sub>   | Polypropylene with TiO <sub>2</sub>              |
| O-rings                                      | Silicone elastomer                     | Silicone elastomer                               |

Note: For CLxMSTGQP1, x = M05 for a unit with a bed volume of 10 mL, 3 for a unit with a bed volume of 60 mL. For NTxMSTGQP1, 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<sup>1</sup>

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

<sup>1</sup>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) <sup>2</sup> | Product code              |
|-----------------|-----------------------------------|--|---------------------------|
| 10              | 500                               | 0.245 (17 mL/min/psi)                      | CLM05MQTGSP1              |
| 60              | 3000                              | 1.25 (86 mL/min/psi)                       | CL3MSTGQP1                |
| 260             | 13000                             | 3.90 (269 mL/min/psi)                      | NP6MSTGQP1/<br>NT6MSTGQP1 |
| 520             | 26 000                            | 7.80 (538 mL/min/psi)                      | NP7MSTGQP1/<br>NT7MSTGQP1 |
| 780             | 39 000                            | 11.70 (807 mL/min/psi)                     | NP8MSTGQP1                |

<sup>2</sup>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

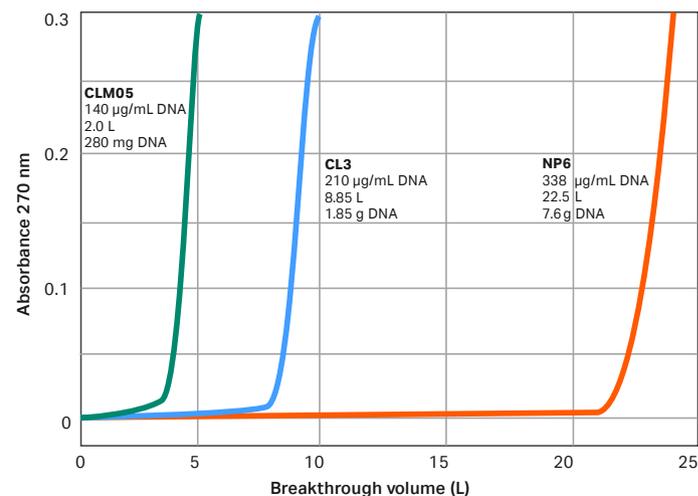


Fig 2. DNA breakthrough curves on Mustang Q capsules.

The DNA breakthrough curves in Figure 2 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, 210 and 338 µg/mL of herring sperm DNA in 25 mM Tris-HCl pH 8.0 was pumped respectively through the 10, 60 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.

## Nominal dimensions for capsules

| Capsule type                      | CLM05MSTGQP1     | CL3MSTGQP1       | NP6MSTGQP1        | NP7MSTGQP1        | NP8MSTGQP1        | NT6MSTGQP1        | NT7MSTGQP1        |
|-----------------------------------|------------------|------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| 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.)  | 240 mm (9.5 in.)  | 240 mm (9.5 in.)  |
| Length including sanitary valves  | 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.) | 349 mm (13.7 in.) | 598 mm (23.5 in.) |
| Bed volume (mL)                   | 10               | 60               | 260               | 520               | 780               | 260               | 520               |

## Ordering information

| Product           | Pkg   | Connection                                 | Bed volume (mL)    | Product code |              |
|-------------------|-------|--|--------------------|--------------|--------------|
| Mustang Q capsule | 1/box | 1 to 1½ in. compatible sanitary connection | In-line connection | 10 mL        | CLM05MSTGQP1 |
|                   |       |  |                    | 60 mL        | CL3MSTGQP1   |
|                   |       |  |                    | 260 mL       | NP6MSTGQP1   |
|                   |       |  |                    | 520 mL       | NP7MSTGQP1   |
|                   |       |  |                    | 780 mL       | NP8MSTGQP1   |
|                   |       | T-style connection                         | 260 mL             | NT6MSTGQP1   |              |
|                   |       |  | 520 mL             | NT7MSTGQP1   |              |

For more information, contact Cytiva.

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