PALL Life Sciences

Validation Guide

USTR 2500

Mustang® Q XT5000 Membrane Chromatography Capsules

*Filtration. Separation. Solution.*SM

Contents

1. Overview

1.1 Introduction

Pall Mustang® Q XT5000 membrane chromatography capsules (Part Number T5000MSTGQP1) are designed to simplify and reduce the operational requirements of the production processes in the manufacture of biopharmaceuticals. The mechanism involved is rapid surface anion exchange adsorption within the convective pores of the membrane. Mustang Q membranes are manufactured from a low protein binding polyethersulfone (PES) 0.8 µm membrane having anion exchange functional groups. The membrane is coated with a polymer having pendant quaternary amine groups and then the polymer is irreversibly cross-linked, resulting in high dynamic binding capacities at very high flow rates. The Mustang Q XT5000 capsule contains 16 layers of membrane in a unique laid-over pleat configuration, which maximizes the amount of membrane packaged within its housing. The total membrane bed volume is nominally 5 liters, and the polypropylene capsule has been designed to improve flow dynamics and reduce hold up volume. Scale down tests for optimization may be performed using the Mustang Q XT140 (Part Number XT140MSTGQP05) and the Mustang Q XT5 chromatography capsule (Part Number XT5MSTGQPM6).

1.2 Purpose

The purpose of this report is to summarize the tests that were performed to qualify the performance of Mustang Q XT5000 capsules under standard conditions. This testing program included:

- Extractables testing before and after preconditioning
- Determination of flow characteristics
- Integrity and dispersion testing
- Determination of BSA (bovine serum albumin) dynamic binding capacity
- Sanitization and storage
- Dry storage shelf life
- Biological reactivity tests on the materials of construction

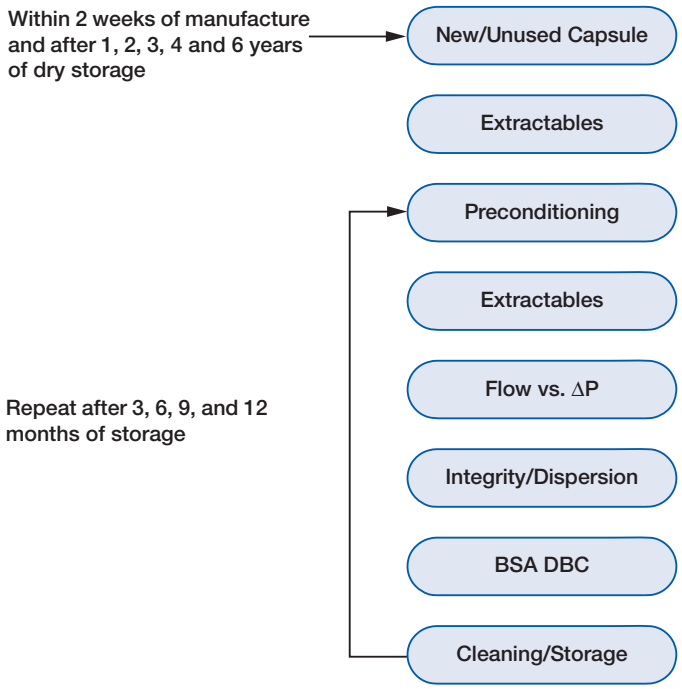
Warning: Mustang Q products should not be used with fluids that are incompatible with its materials of construction. Incompatible fluids are those that chemically attack, soften, stress, crack, or adversely affect the materials of construction in any way. Fluids that should not be used include cleaning agents and fluids containing organic solvents such as alcohol.

1.3 Summary of Protocols

Figure 1 outlines the series of tests that were performed to validate the performance of the Mustang Q XT5000 membrane chromatography capsules. Tests were run on capsules when new and at intervals of 3, 6, 9, and 12 months when stored wet. Nine capsules were enrolled in the wet storage study, 3 each from 3 different membrane lots. A parallel study is also underway to validate the performance of capsules that have been stored dry and unused for 1 to 5 years. For this study, each capsule is only tested once as an unused capsule, and data is compared to capsules that were originally tested immediately after manufacture.

Figure 1

Tests Performed to Validate Performance of Mustang Q XT5000 Membrane Chromatography Capsules



1.3.1 Extractables Before and After Preconditioning

Extractables were measured in water flushes before and after preconditioning. The amount of non-volatile residue (NVR) and total organic carbon (TOC) from preconditioned Mustang Q XT5000 capsules was found to be very low. Preconditioning procedures are effective in reducing NVR up to 7-fold and TOC up to 20-fold. Actual service will impose different conditions, such as different exposure times, temperature, liquid purity etc. Evaluation under process conditions is therefore also recommended.

1.3.2 Determination of Flow Characteristics

The Mustang Q XT5000 capsule was equilibrated with 20 mM Tris, pH 8.0 and run over a range of flow rates. At each flow rate, the inlet and outlet pressures were measured, and the pressure drop across the capsule was calculated. The pressure drop was plotted against the flow rate. Over the flow rate range of 25 – 100 L/min (0.5 – 20 membrane volumes/min), the pressure drop was linear, and the inlet pressure did not exceed the pressure tolerance for the capsule. The results can be used to assist the user when sizing systems that employ Mustang Q XT5000 capsules when used with process fluids of similar viscosities.

1.3.3 Integrity and Dispersion Tests

Adenosine monophosphate (AMP) is used as a marker for integrity and dispersion. For integrity, AMP is injected under binding conditions, and the absorbance at 260 nm is monitored. Any breach in integrity will be detected in the absorbance trace during the injection step. All of the units included in the validation program were integral, and subsequent elution of the bound AMP indicated low dispersion on the downstream side of the membrane. For total dispersion, AMP is injected again under non-binding conditions, and absorbance at 260 nm is also monitored. The AMP should pass through the unit unimpeded and emerge as a single peak with only minor tailing. All of the units that were included in the validation program exhibited low and uniform total dispersion.

1.3.4 Determination of BSA (Bovine Serum Albumin) Dynamic Binding Capacity

The tests performed indicate that Mustang Q XT5000 capsules exhibit extremely high BSA dynamic binding capacity and are therefore suitable for downstream processing applications for the capture of biomolecules or removal of contaminants such as DNA, viruses, host cell proteins, and endotoxins.

After equilibration with 20 mM Tris, pH 8.0, the Mustang Q XT5000 capsule was loaded to saturation with a solution of 1.2 mg/mL BSA in equilibration buffer. After loading was complete, any unbound BSA was washed out, and bound BSA was eluted with a single step of 1 M NaCl in 20 mM Tris, pH 8.0. Dynamic binding capacity was determined from the amount of BSA that was present in the elution fraction. Typical binding capacities for each capsule were approximately 75 grams of BSA per liter of membrane volume.

1.3.5 Sanitization and Storage

Sanitization is performed using 1 M NaOH. The capsule can then be stored in 0.1 M NaOH plus 1 M NaCl.

1.3.6 Biological Reactivity Tests on the Materials of Construction

Prior to performing the biological reactivity tests, Mustang XT5000 capsule materials of construction were conditioned using recommended procedures. The materials used in the construction of the polypropylene capsule housing, polypropylene end cap, the polypropylene support and drainage nets, and the Mustang Q XT membrane all met the requirements of the USP for Class VI (50 °C) Plastics *(in vivo)*.

2. Extractables Testing Before and After Preconditioning

2.1 Introduction

The purpose of this series of tests was to analyze and quantify the amount of material that can be extracted from new Mustang Q XT5000 capsules by water at ambient temperature (20 °C ± 5 °C) before and after preconditioning.

2.2 Summary of Methods

Typical Mustang Q XT5000 capsules were first evaluated for extractables as new unused capsules. Equipment used in these tests (pump, tubing, connectors) was sanitized by exposure to 1 M NaOH for 30 minutes and rinsed with deionized water prior to connecting to the Mustang Q XT5000 capsule.

The Mustang Q XT5000 capsule was connected to the pump, and 20 liters of deionized water was recirculated through the capsule at a flow rate of 10 L/min for a period of 30 minutes. The pump was stopped, and samples of the recirculated water were taken for TOC (total organic carbon) and NVR (non-volatile residue) analysis.

The Mustang Q XT5000 capsule was preconditioned at 10 L/min with:

- 25 liters of 1 M NaOH
- 25 liters of 25 mM H_3PO_4/1 M NaCl

Following preconditioning, the Mustang Q XT5000 capsule was equilibrated to neutral pH using 20 liters of 20 mM sodium phosphate buffer, pH 7.0, and then flushed with 40 liters of deionized water to reduce conductivity.

Following the last step, 20 L of deionized water was recirculated through the capsule at a flow rate of 10 L/min for a period of 30 minutes. The pump was stopped, and samples of the recirculated water were taken for TOC and NVR analysis.

2.3 Results

The amount of extractables (NVR and TOC) obtained from Mustang Q XT5000 capsules is shown in Table 1. Results shown are the average of nine capsules from three different membrane lots.

Table 1
Extractables

TOC Before Preconditioning (mg/L of extract)	TOC After Preconditioning (mg/L of extract)	NVR Before Preconditioning (mg/L of extract)	NVR After Preconditioning (mg/L of extract)
13.43	0.93	80.05	11.50

2.4 Conclusions

The preconditioning procedure reduces the levels of aqueous extractables to an extremely low level. TOC levels were reduced approximately 15-fold, and NVR levels were reduced 7 to 8-fold.

Caution: It is essential that end users follow the 2-step preconditioning protocol prior to first use, between cycles, and after prolonged storage. Preconditioning ensures low levels of extractables prior to equilibration with the appropriate buffer.

Actual service will impose different conditions, such as different exposure times, temperature, liquid purity etc. Evaluation under process conditions is therefore also recommended.

3. Flow vs. Differential Pressure

3.1 Introduction

The aim of this series of tests was to determine the pressure drop across the Mustang Q XT5000 capsules at different flow rates using an aqueous test fluid.

3.2 Summary of Methods

The Mustang Q XT5000 capsule was first equilibrated with 20 mM Tris, pH 8.0 until the pH and conductivity of the effluent were equal to that of the buffer in the tank. At that point, the test was run in recirculation mode.

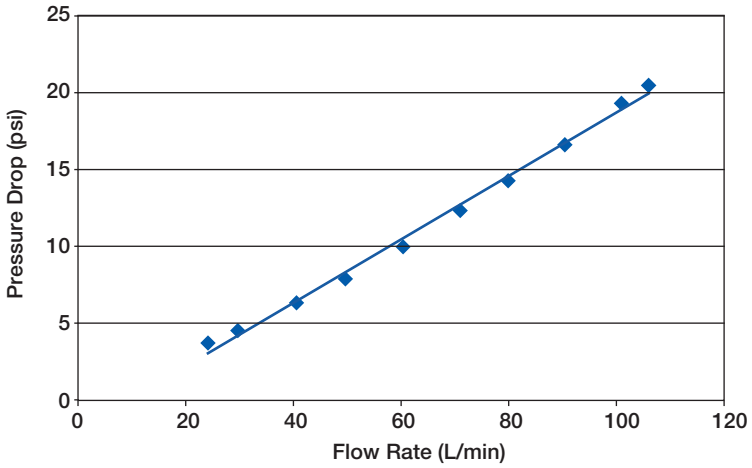
The flow rate was set at 25 L/min (5 membrane volumes/minute), and the pressure was measured on both the inlet and outlet sides of the device. The flow rate was then raised in increments to a final flow rate of 100 L/min (20 membrane volumes/min). At each flow rate, inlet and outlet pressures were measured. For each flow rate, the pressure drop was calculated by subtracting the outlet pressure from the inlet pressure.

3.3 Results

A graph of the flow of the Tris buffer versus pressure drop is shown in Figure 2.
Nine capsules (three each from three different lots) were used in performance of the test.

Figure 2

Flow versus Differential Pressure for Mustang Q XT5000 Capsules, Part Number XT5000MSTGQP1



3.4 Conclusions

The Mustang Q XT5000 capsule exhibited a linear pressure drop throughout the entire range of flow rates tested (25 – 100 L/min), and the inlet pressure did not exceed the pressure tolerance for the capsule. The pressure curves were consistent from capsule to capsule and from lot to lot.

The flow characteristics described in this report can be used to assist in sizing systems employing Mustang Q XT5000 capsules when used with process fluids of similar viscosities.

4. Integrity and Dispersion

4.1 Introduction

The Mustang Q XT5000 capsule comes ready to run without the need for column packing and qualification associated with conventional chromatography resins. However, because the configuration of the capsule is much like that of a filter, a test is necessary to demonstrate that the capsule is integral without any defects in the membrane or other components that would allow bypass of the membrane. In addition, because the capsule is a chromatography device, a test is also necessary that gives the end user an assessment of the fluid flow characteristics of the capsule as a whole. For both of these purposes, a test has been developed that utilizes a common non-toxic negatively charged molecule — adenosine monophosphate (AMP) — to determine both the integrity of the capsule and its dispersion characteristics.

A total of 9 capsules have been tested, 3 each from 3 different membrane lots.

4.2 Summary of Methods

4.2.1 Integrity

For the integrity test, AMP is introduced into the Mustang Q XT5000 capsule under binding conditions. The capsule was first equilibrated with 20 mM Tris, pH 8.0 until the pH and conductivity of the effluent were equal to that of the buffer in the tank.

A solution of 3 mg/mL AMP in 20 mM Tris, pH 8.0 was prepared, and 500 mL of that solution was pumped into the injection loop of the chromatography system. The system pump was then started at 50 L/min, and the AMP is swept onto the Mustang Q XT5000 capsule. Absorbance at 260 nm was monitored. A capsule that has no breach in integrity will show no change in UV absorbance during the injection step – all of the AMP should bind to the membrane.

Following the injection, the AMP was eluted with a single step of 1 M NaCl in 20 mM Tris, pH 8.0. Absorbance at 260 nm continued to be monitored, and AMP should elute as a single sharp peak.

4.2.2 Dispersion

For the dispersion test, AMP is introduced into the Mustang Q XT5000 capsule under non-binding conditions. The test was run immediately following the integrity test since the capsule is already in 1 M NaCl in 25 mM Tris, pH 8.0 at the end of that test.

A solution of 3 mg/mL AMP was prepared in 1 M NaCl in 25 mM Tris, pH 8.0, and 500 mL of that solution was pumped into the injection loop of the chromatography system. The system pump was then started at 50 L/min, and the AMP was swept onto the Mustang Q XT5000 capsule. Absorbance at 260 nm was monitored.

Under these conditions, AMP should not bind and should emerge from the capsule as a single peak following the injection step with no shouldering and minimal tailing. This indicates uniform flow distribution through the entire capsule.

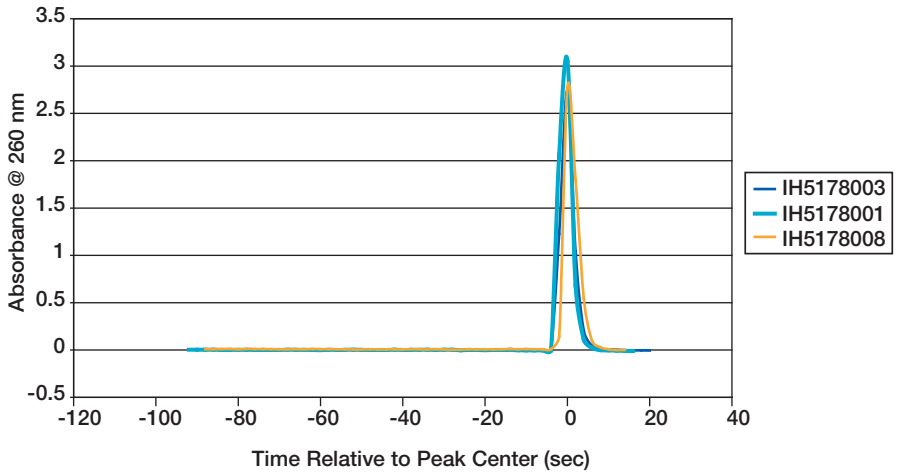
4.3 Results

4.3.1 Integrity

All 9 of the capsules tested in this study proved to be integral. There was no evidence of breakthrough during the injection step, and the AMP eluted as a single sharp peak. Figure 3 shows an overlay of the integrity curves for three of these capsules. All other capsules showed a similar integrity profile.

Figure 3

Integrity Curves for Mustang Q XT5000 Disposable Chromatography Capsules

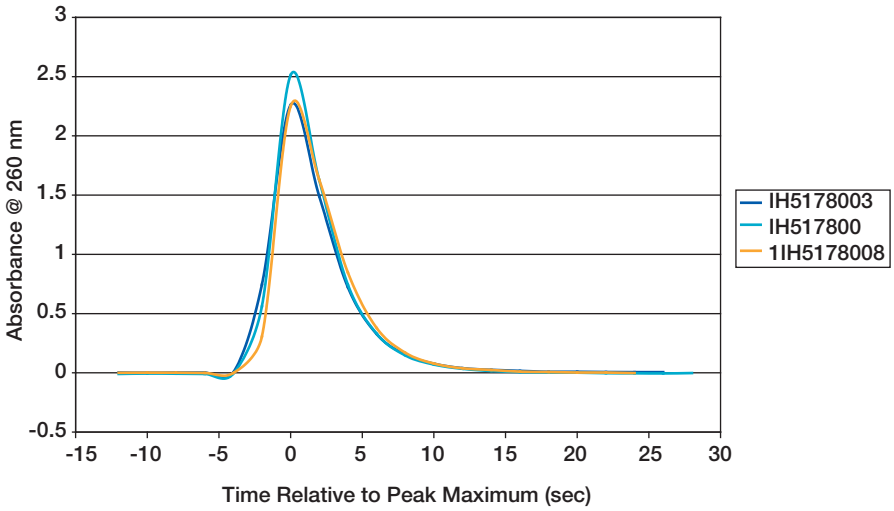


4.3.2 Dispersion

Each of the 9 capsules tested in this study showed similar dispersion patterns. The AMP peak emerged from the capsule with a sharp leading edge, no shouldering, and minimal tailing on the trailing edge. Figure 4 shows an overlay of the dispersion curves for three of these capsules. All other capsules exhibited a similar dispersion pattern.

Figure 4

Dispersion Patterns for Mustang Q XT5000 Disposable Chromatography Capsules



4.4 Conclusions

AMP is a useful marker to demonstrate both integrity and fluid dispersion in the Mustang Q XT5000 capsule. In addition, it also identifies the membrane within the capsule as an anion exchanger, since AMP binds under conditions of low conductivity as seen in the integrity test. These two tests give the end user assurance that the capsule is integral and shows relatively uniform flow distribution before committing it to the purification of high value products. Each of these tests can be completed in a matter of minutes.

A patent application for this technique is pending.

5. Determination of BSA Dynamic Binding Capacity

5.1 Introduction

The aim of this series of tests was to determine the BSA dynamic binding capacity of the Mustang Q XT5000 capsule.

5.2 Summary of Methods

Typical Mustang Q XT5000 capsules from standard production lots were tested. A total of 9 capsules were tested, 3 each from 3 different membrane lots. The flow rate throughout every run was 50 L/min — 10 membrane volumes (MV)/min.

The Mustang Q XT5000 capsule was equilibrated with a sufficient volume of buffer (20 mM Tris, pH 8.0) such that the pH recorded at the outlet is equal to the original pH of the buffer, and remained constant for an additional 2 membrane volumes. At this point, the UV detector was zeroed to establish baseline.

A solution of 1.2 mg/mL BSA in 20 mM Tris, pH 8.0 was loaded, and the UV absorbance of the fluid collected on the downstream side was monitored at 280 nm. The point at which the absorbance rises to 0.1 AU (absorbance units) above baseline is considered the breakthrough point. BSA loading continued until the UV absorbance reached a plateau and was continued for another 2 MV to assure complete saturation of the membrane.

Once the loading was completed, unbound BSA was washed out until the UV absorbance returned to baseline and held there for 2 membrane volumes.

Bound BSA was eluted with a single step of 1 M NaCl in 20 mM Tris, pH 8.0. The elution peak was collected from the moment that the UV absorbance began to rise to the moment it returned to baseline. The volume of the elution peak was measured, the BSA concentration was determined, and the mass of BSA in the elution fraction was calculated. Dividing the mass of

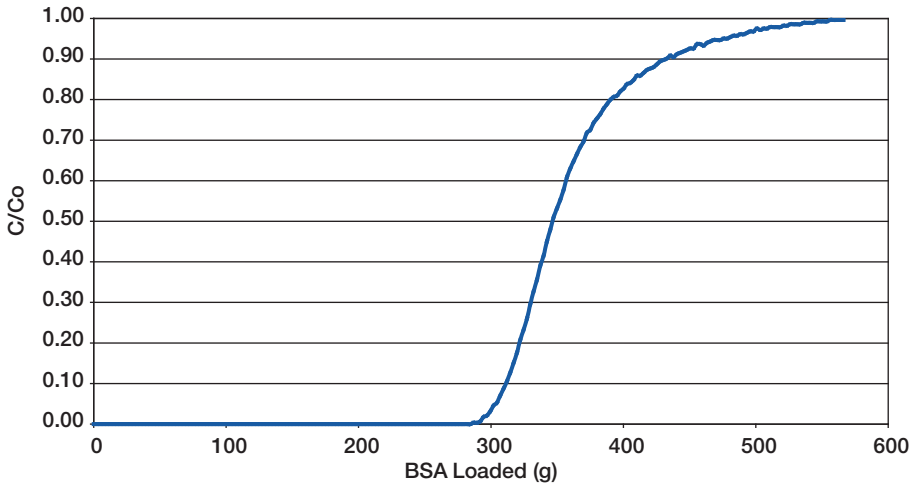
BSA in the elution fraction by 5 gives the binding capacity of the Mustang Q XT5000 capsule for BSA in units of grams/liter of membrane.

5.3 Results

Figure 5 shows a typical dynamic binding curve from capsule IH5178008. The ratio of the BSA concentration in the effluent and the concentration in the feed is determined and plotted against the mass of BSA loaded. Initial breakthrough occurs after 300 g of BSA have been loaded.

Figure 5

Binding Capacity Curve for Mustang Q XT5000 Capsule, Part Number XT5000MSTGQP1

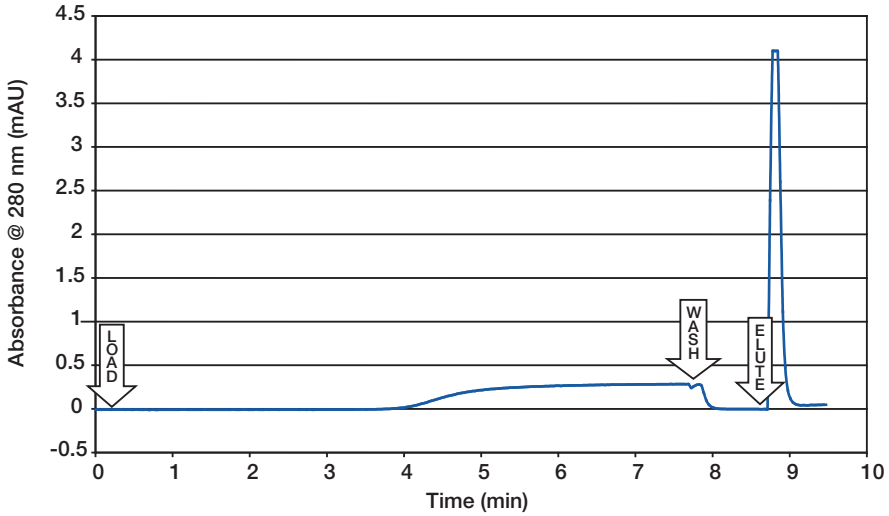


C/Co is the ratio of the BSA concentration in the effluent and in the original feed.

Figure 6 shows the full chromatogram from the same capsule. Arrows on the chromatogram indicate where the load, wash, and elute steps take place. Initial breakthrough does not occur until after 4 minutes have elapsed, and full saturation is achieved in 8 minutes. Wash and elution take only 2 minutes. These three steps together take place in less than 10 minutes, and approximately 400 g of BSA were bound and eluted in total.

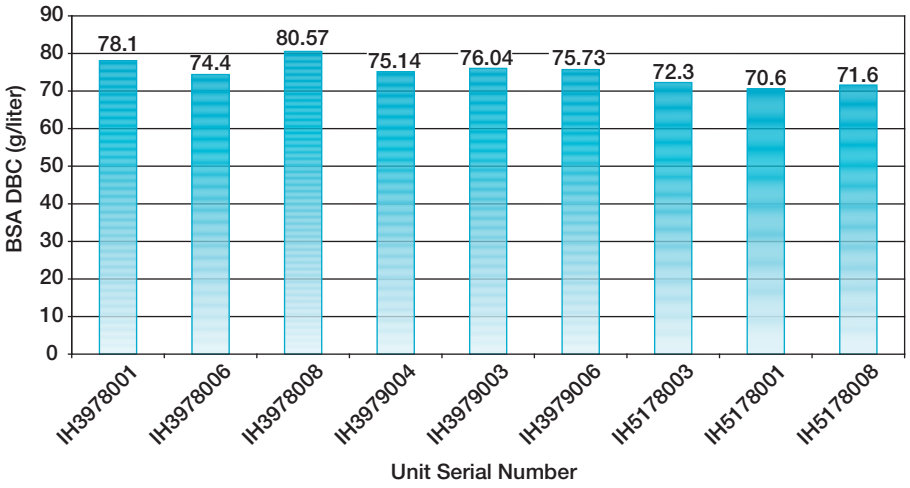
Figure 6

Typical Dynamic Binding and Elution Curve for Mustang Q XT5000 Capsule, Part Number XT5000MSTGQP1



Dynamic binding capacities for nine Mustang Q XT5000 capsules are shown in Figure 7. The average binding capacity is 75 ± 3 grams of BSA per liter of membrane volume.

Figure 7
BSA Dynamic Binding Capacities at 80% Breakthrough for Mustang Q XT5000 Capsules, Part Number XT5000MSTGQP1



5.4 Conclusions

Mustang Q XT5000 capsules exhibit high BSA dynamic binding capacities and are therefore suitable for downstream bioprocessing applications for the capture and elution of negatively charged target molecules. This test demonstrates both the high speed and high capacity of the Mustang Q XT5000 capsule.

Other target molecules will have different binding capacities when run on Mustang Q membrane. Also, different flow rates and the presence of host cell protein or other contaminants may influence the performance, and it is therefore recommended that the user evaluate Mustang Q XT5000 capsules using specific process fluids under standard operating conditions.

6. Sanitization and Storage

6.1 Introduction

Users of Mustang Q XT5000 capsules may wish to use sodium hydroxide for sanitization purposes. Conditions for sanitization and storage of Mustang Q XT5000 capsules have been established that have no effect on extractables, differential pressure, and dynamic binding capacity. To ensure reliable performance, users should follow these procedures exactly as described in this section.

6.2 Summary of Methods

6.2.1 Sanitization with 1 M NaOH

Thirty liters of 1 M NaOH were prepared, and 5 bed volumes (25 L) were pumped through the Mustang Q XT5000 capsule at a flow rate of 10 L/min. The pump was stopped, and the capsule was held for 30 minutes.

6.2.2 Preparation for Storage

Thirty liters of 0.1 M NaOH/1 M NaCl were prepared, and 5 bed volumes (25 L) were pumped through the Mustang Q XT5000 capsule at a flow rate of 10 L/min. The pump was stopped, and the capsule positioned over a drain. The lines attached to the outlet side and inlet side of the capsule were disconnected, and the drainage vent on the bottom of the capsule was opened to allow the capsule to drain out completely. The capsule was inverted over the floor drain to allow complete drainage

of the upstream side. Plastic blank end caps were fastened to the outlet and inlet sides of the device using a silicone gasket and clamp, and both vent valves were completely closed. The capsule was stored on its side at room temperature.

6.2.3 Determination of extractables, differential pressure, dispersion, integrity, and dynamic binding capacity after sanitization and storage

Mustang Q XT5000 capsule were sanitized and prepared for storage as described above. At intervals of 3, 6, 9, and 12-month time points, each capsule was taken out of storage, pre-conditioned, and reevaluated for extractables, differential pressure, integrity, dispersion, and BSA dynamic binding capacity. Results after storage are then compared with the results that were generated when the capsules were first tested.

6.3 Results

6.3.1 Extactables

At 3, 6, 9 and 12 month time points, the nine capsules that were originally tested as new were taken out of wet storage, conditioned using the protocol in Section 2.2, and retested for TOC and NVR. Table 2 shows that over the 12 month period there was no significant change in either TOC or NVR at any of the time points tested during the wet storage test, indicating that the materials of construction are stable under the storage conditions used.

Table 2

*Non-volatile Aqueous Extractables and TOC Measurements**

Time Point	TOC After Preconditioning (mg/L of extract)	NVR After Preconditioning (mg/L of extract)
New capsules	0.96 ± 0.49	11.11 ± 6.12
3 months	0.60 ± 0.96	176.87 ± 399.13
6 months	1.56 ± 3.63	59.78 ± 74.58
9 months	0.16 ± 0.16	39.06 ± 45.92
12 months	0.18 ± 0.10	11.69 ± 13.60

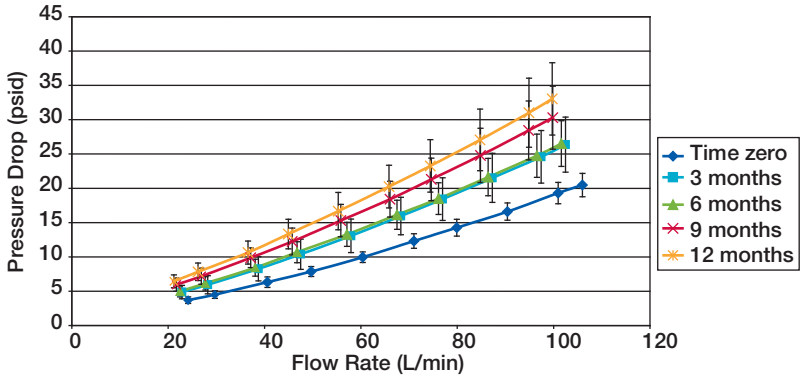
** Obtained using typical Mustang Q XT5000 capsules, Part Number XT5000MSTGQP1, under conditions of prolonged wet storage*

6.3.2 Flow vs. Pressure Drop

Following the test for extractables, the nine capsules in the validation study that were originally tested as new were then tested for flow vs. pressure drop using the same procedure as described in Section 3.2. Figure 8 shows the average pressure drop for all nine capsules at each of the time points tested after wet storage began. Although there is a slight increase in pressure drop over time during wet storage, the pressure limits of the membrane and the capsule were never exceeded.

Figure 8

Flow vs Pressure Drop after Prolonged Storage

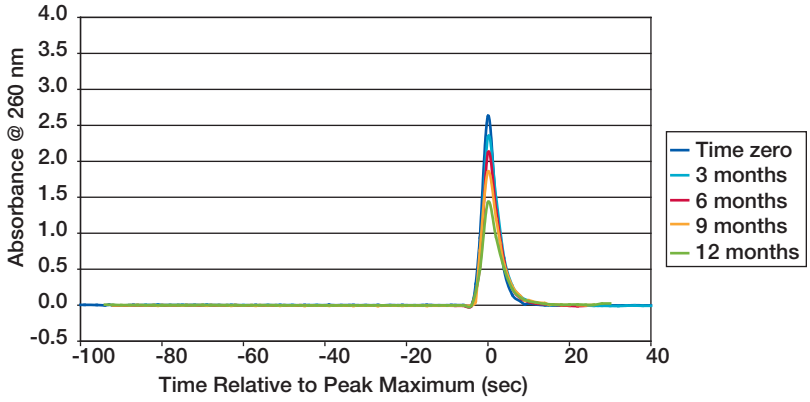


6.3.3 Integrity

Capsules in the wet storage study were tested for integrity using the same protocol as described in Section 4.2, and the results were compared to when the capsules were originally tested as new. Figure 9 shows the integrity test curves at first test, and after 3, 6, 9, and 12 months of wet storage. Each curve is the average of all nine capsules tested at each time point. There is no evidence of integrity loss over the course of twelve months of wet storage, indicating that the integrity of the membrane and the capsule is not affected by long term wet storage using the recommended storage solution.

Figure 9

Integrity after Prolonged Wet Storage

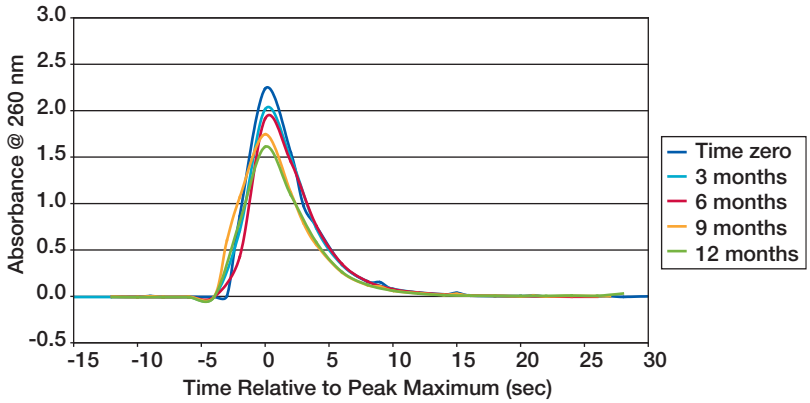


6.3.4 Dispersion

Capsules in the wet storage study were tested for dispersion using the same protocol as described in Section 4.2, and the results were compared to when the capsules were originally tested as new. Figure 10 shows the dispersion curves at first test, and after 3, 6, 9, and 12 months of wet storage. Each curve is the average of all nine capsules tested at each time point. There is no evidence of changes in dispersion over the course of twelve months of wet storage, indicating that the flow characteristics of the membrane and the capsule are not affected by long term wet storage using the recommended storage solution.

Figure 10

Dispersion after Prolonged Wet Storage

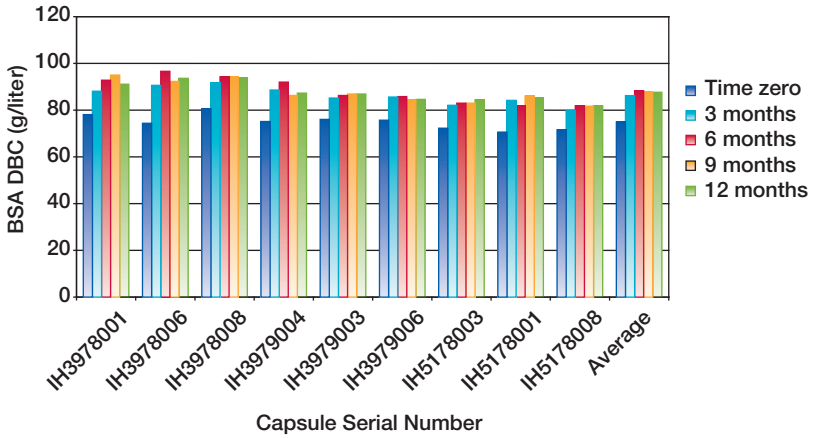


6.3.5 BSA Dynamic Binding Capacity

Capsules in the wet storage study were tested for dynamic binding capacity using the same protocol as described in Section 5.2, and the results were compared to when the capsules were originally tested as new. Figure 11 shows the DBC values for each capsule at first test, and after 3, 6, 9, and 12 months of wet storage. The average for all capsules over the course of the study is also shown. Although there is a slight increase in DBC with prolonged wet storage, it is stable over time and is not decreasing, indicating that the binding capacity of the membrane is not adversely affected by long term wet storage using the recommended storage solution.

Figure 11

BSA DBC after Prolonged Wet Storage



6.4 Conclusions

Sanitization with 1 M NaOH and long-term storage in 0.1 M NaOH/1M NaCl is shown to have minimal effect on the performance of the Mustang Q XT5000 capsule over the course of 1 year. Measures of performance for individual capsules as well as the average of all nine capsules remain within specification after as long as 12 months of storage in the storage solution.
End users can, therefore, use Mustang Q XT5000 membrane chromatography capsules multiple times with periods of storage in between uses and expect no deterioration in performance associated with prolonged wet storage.

7. Dry Storage Shelf Life

7.1 Introduction

This study was designed to determine the shelf life of the Mustang Q XT5000 capsules during dry storage in their original packaging.

7.2 Summary of Methods

The same methods described in sections Section 1.2.2, Section 1.2.3 and Section 1.2.4 were used following the steps detailed in Section 1.2.1.

7.3 Results

At the time of the writing of this document, results after three years of storage have been obtained with testing having been performed at yearly intervals. The temperature fluctuations during this time ranged from 13 °C to 27 °C. These data indicate that dry storage under the conditions described have not had any effects on the product's performance.

7.4 Conclusion

This study has determined that the Mustang Q XT5000 capsules have a shelf life of at least three years in real time. There are three more yearly data points that have yet to be determined.

8. Biological Reactivity Tests on the Materials of Construction

8.1 Introduction

The purpose of this study was to evaluate the biological compatibility of the materials of construction used in the Mustang Q XT5000 capsule. This includes the materials used in the capsule, and the support and drainage nettings.

8.2 Summary of Methods

A single Mustang Q XT5000 capsule was used for this test. The capsule was initially pre-conditioned by the same procedure as described in Section 2. At the end of the preconditioning process, the capsule was flushed with deionized water, and drained. The capsule was then cut apart, and samples of the capsule materials, support netting, and drainage netting were obtained.

The tests were performed in accordance with the Biological Reactivity Tests *in vivo* for Class VI Plastics (50 °C) as described in the current United States Pharmacopeia.

The tests were conducted by:

STS division of Ethox Corp. Rush, NY, USA.

The testing procedures described in the USP include:

- Injection of extracts of the test article
- Implantation of the test article into animal tissue

The four extracting media listed in the USP simulate parenteral solutions and body fluids. These include:

- Sodium Chloride for Injection
- 1 in 20 Solution of Alcohol in Sodium Chloride Injection
- Polyethylene Glycol 400
- Vegetable Oil (sesame or cottonseed oil)

The USP states that extracts may be prepared at one of three standard conditions: 50 °C for 72 hours, 70 °C for 24 hours, or 121 °C for 1 hour. The Mustang Q XT5000 capsule materials of construction were tested at 50 °C for 72 hours.

8.2.1 Acute Systemic Injection Tests

An Acute Systemic Injection Test was performed to evaluate the potential of a single injection of an extract to produce systemic toxicity. Sodium Chloride Injection and 1 in 20 Solution of Alcohol in Sodium Chloride Injection were injected intravenously. Vegetable oil extract and Polyethylene Glycol 400 extract were injected intra-peritoneally.

8.2.2 Intracutaneous Tests

An Intracutaneous Test was performed to evaluate the potential of a single injection of an extract to produce tissue irritation. All four of the extracts listed above were used for these tests.

8.2.3 Implantation Tests

Implantation tests were also performed, in order to subject the material of construction to the most stringent conditions included in the USP.

8.3 Results

No biological response was observed in any of the tests performed. Therefore, all materials of construction have passed USP Class VI testing. Results are on file at Pall Corporation.

8.4 Conclusions

Following preconditioning, the materials of construction used in the Mustang Q XT5000 capsule meet the requirements for biocompatibility under standard conditions as outlined by the USP.

New York – United States
800.717.7255 toll free (USA)
516.484.5400 phone
516.801.9548 fax
biotech@pall.com e-mail

Portsmouth – Europe
+44 (0)23 9230 3303 phone
+44 (0)23 9230 2506 fax
BioPharmUK@europe.pall.com e-mail

Filtration. Separation. Solution.SM

Visit us on the Web at www.pall.com/biopharm
E-mail us at biotech@pall.com

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