Graver Technologies

FILTRATION | SEPARATION | PURIFICATION

QMA™ Series Filter Cartridges

Qualification Guide

"Absolute" Rated High-Performance Pleated Polypropylene Filter Cartridge

Quality System: ISO 9001:2015 Registered Manufacturing Facility
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Preface

Each section of this Qualification Guide presents only a summary of the corresponding test method. If your organization requires expanded detail on any particular test method, or the underlying raw data, please contact the Graver Technologies Liquid Filter Group for assistance.

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Introduction

The Graver Technologies QMA™ pleated filter cartridges are engineered as an exceptionally clean, non-leaching, non-shedding barrier for membrane and fine-particle filtration. These filters deliver reliable, repeatable performance in removing inert contaminants larger than their rated pore size.

All QMA cartridges incorporate polypropylene melt blown media that provides a filtration efficiency of 99.98% (Beta 5000) per ASTM F795-88, the Standard Practice for Determining the Performance of a Filter Medium Employing a Single-Pass, Constant-Rate Liquid Test. Every QMA cartridge component — cage, core, end caps and support layers — is manufactured entirely from polypropylene, which conforms to both the CFR requirements for Indirect Food Additives and USP Class VI standards. QMA cartridges can be sanitized with steam, hot water, or compatible chemicals, and are fabricated in an ISO 9001:2015 registered manufacturing facility.

This guide summarizes the results of laboratory qualification testing performed on Graver Technologies QMA cartridge filters, covering:

- Flow Rate Testing
- Core Collapse (Differential Pressure Stress) Testing
- Sanitization and Sterilization Testing
- Endotoxin Testing
- Extractables (Non-Volatile Residue) Testing
- Food-Contact Compliance (EU 1935/2004 and 10/2011)
- Bio-Safety Testing

QMA Information

The following key specifications are drawn from the current QMA product datasheet and provide quick reference context for the qualification results that follow.

Parameter	Specification
Media	Melt blown polypropylene (up to 7.0 ft² / 0.65 m²)
Micron ratings	0.2, 0.45, 1, 2.5, 5, 10, 20 µm
Efficiency	“Absolute” 99.98% (Beta 5000)
Outside / Inside diameter	2.7 in (6.86 cm) / 1.0 in (2.54 cm)
Max. operating temperature	176°F (80°C)
Max. differential pressure	75 psid @ 70°F (5.2 bar @ 21°C); 30 psid @ 176°F (2.0 bar @ 80°C)
Max. reverse pressure	40 psid @ 70°F (2.8 bar @ 21°C)
Recommended change-out	35 psid (2.4 bar)

Construction

Materials of Construction

Component	Material
Media	Melt blown polypropylene — 7.0 ft² (0.65 m²)
Drainage layer	Polypropylene
Core	Polypropylene
Cage / outer sleeve	Polypropylene
End caps	Polypropylene
O-rings / gaskets	Viton (standard), Silicone, EPDM, Buna-N, Teflon-encapsulated Viton

Product Traceability

QMA filter elements are manufactured in conformance with established current Good Manufacturing Practice (cGMP) standards. The elements are produced and distributed under a Quality Management System registered for compliance with EN ISO 9001:2015. All data concerning the materials used and the production process are documented, accessible, and fully traceable.

Flow Rate Test

To support the overall operating economics of a filter system, process filter cartridges should offer high flow rates at low pressure drops. For new systems this also allows a smaller filter housing to be used, providing a corresponding saving in capital cost.

Test Procedure

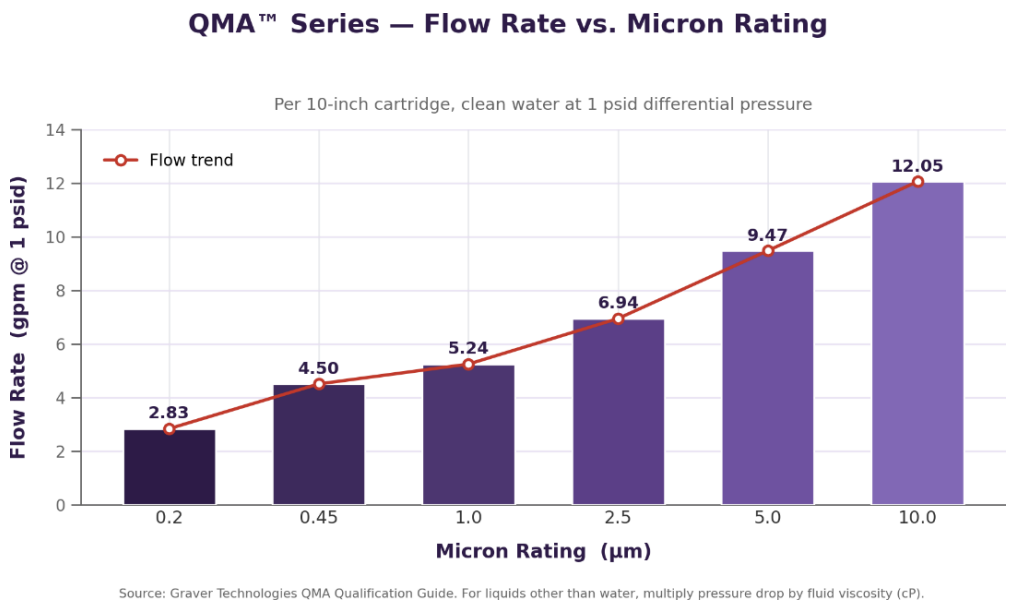
1. A filter cartridge is installed into the test system and wetted with clean water.
2. The filter system is connected to a source of clean water; the water pressure is regulated to 18 psi (1.2 bar).
3. Flow through the filter is adjusted to establish a test differential pressure of 1 psid across the filter.
4. The flow rate through the filter housing is recorded.
5. The test is repeated with several cartridges for each pore size.

Results

Typical flow rate / pressure-drop characteristics of QMA cartridges, per 10-inch cartridge length:

Micron Rating	Flow Rate (gpm / psid)
0.2 µm	2.83
0.45 µm	4.50
1.0 µm	5.24
2.5 µm	6.94
5.0 µm	9.47
10.0 µm	12.05

Note: For liquids other than water, multiply the pressure drop by the fluid viscosity in centipoise.



Core Collapse (Differential Pressure Stress) Test

In normal use a filter cartridge is exposed to an increasing differential pressure as it accumulates contaminants. Routine stops and starts on a production line also subject the filter to numerous differential-pressure surges. The limiting factor in a cartridge's resistance to differential pressure is the strength of its core. The regimen below stresses the QMA core under conditions more rigorous than those normally encountered in service; to pass, the cartridge must remain integral throughout the test.

Test Procedure

1. A filter core, bonded to an adapter suitable for a test housing (e.g., -226 or -222 adapter), is encased in a non-porous film to prevent permeation of the test liquid.
2. The core is installed into the filter housing, which is connected to a hydraulic test system.
3. At ambient temperature, hydraulic pressure is slowly increased until the core collapses.
4. The hydraulic fluid — and therefore the housing and core — is heated to 176°F (80°C).
5. Hydraulic pressure is again slowly increased until the core collapses.

Results

- Cores consistently resisted collapse to well over 100 psid (6.9 bar) at ambient temperature, 70°F (21°C).
- Cores consistently resisted collapse to well over 60 psid (4.1 bar) at an elevated temperature of 176°F (80°C).

Conclusion

Based on this testing and the Graver Technologies QMA fabrication methodology, QMA cartridges can withstand differential pressures up to 75 psid (5.2 bar) at 70°F (21°C) and 30 psid (2.0 bar) at 176°F (80°C) and remain integral.

Sanitization / Sterilization

Steam Sterilization Test

Under certain conditions it may be necessary to steam-sterilize or sanitize the QMA cartridge to reduce extraneous organisms introduced from the environment or from the process fluid. This section outlines the procedures, results, and conclusions used to validate QMA cartridges for steam sterilization and hot-water sanitization.

Test Procedure

1. A cartridge is installed, wetted with clean water, and integrity tested, with data recorded.
2. The system is connected to a source of clean, dry, saturated steam with a maximum pressure of 45 psid (3.1 bar).
3. The filter is steamed at 275°F (135°C) with a maximum differential pressure of 3 psid.
4. After 30 minutes of steam, the cartridge is allowed to cool for 30 minutes.
5. Steps 2–4 are repeated; after every third cycle the cartridge is re-wetted and integrity tested.

Conclusion

QMA cartridges remain integral when steam-sterilized up to 10 times at 275°F (135°C) for 30 minutes per cycle. The autoclave process represents milder conditions and is therefore a viable alternative to steam-in-place; QMA cartridges may be autoclaved for 30 minutes at 250°F (121°C) under no end-load conditions.

Hot-Water Sanitization Test

A convenient method of sanitizing the filter is to flow hot water at 176°F (80°C) through the system for at least 30 minutes after the filter has reached a stable temperature. The required time is operating-condition dependent and should be validated for the user's specific system. Because steam sterilization is far more rigorous than autoclaving or hot-water sanitization, it can be safely assumed that QMA cartridges may be autoclaved or hot-water sanitized at least 10 times under the specified conditions.

Endotoxin Test

Endotoxins are complex polysaccharide molecules (LPS) composed of a lipid (lipid A) and polysaccharide side chains, and are integral components of the outer membrane of Gram-negative bacteria. They are not secreted but are released only when cells are disrupted or destroyed. Above certain levels, endotoxins elicit an antigenic response resulting in fever and altered resistance to bacterial infection; it is therefore important to monitor products that may contact fluids administered to humans or animals.

Detection is performed using the Limulus Amebocyte Lysate (LAL) Kinetic Chromogenic Assay. A filter element is extracted with non-pyrogenic Water for Injection (WFI); endotoxin levels in the extract are measured spectrophotometrically against standard concentrations and reported as EU/mL.

Results

Measurement	QMA Result	Acceptance Criterion
Endotoxin concentration	0.019 EU/mL	US FDA ≤ 0.5 EU/mL
Endotoxin per device	5.7 EU/device	USP ≤ 20 EU/device

Testing conducted by NAMSA, Northwood, Ohio. Results are well below both the US FDA and USP limits.

Non-Volatile Residue (Extractables)

This test measures the quantity of impurities extracted from plastics when leached with an extraction medium (purified water) over a specified time and temperature.

Results

Measurement	QMA Result	USP 661 Limit
Non-volatile residue	1 mg	≤ 15 mg

Testing conducted by NAMSA, Northwood, Ohio. The QMA result indicates no significant non-volatile extractables and meets the USP 661 Physicochemical Test for Plastics.

European Regulation No. 1935/2004 and No. 10/2011

The underlying principle of these regulations is to ensure that any material or article intended to come into contact, directly or indirectly, with food is sufficiently inert that substances are not transferred to food in quantities large enough to endanger human health or to cause an unacceptable change in the composition, taste, or properties of the food. Migration testing for direct food contact was conducted by the Belgium Packaging Institute across a range of simulants representing aqueous, acidic, alcoholic, and fatty foodstuffs.

Results

The overall migration of all individual parts did not exceed the overall migration limit of 10 mg/dm² (60 mg/kg foodstuff) for the following simulants:

- Simulant A — 10% ethanol (all aqueous foodstuffs)
- Simulant B — 3% acetic acid (all foodstuffs with pH below 4.5)
- Simulant D2 — 95% ethanol / isooctane in place of olive oil (all fatty foodstuffs)

Conclusion

In accordance with EU Regulation No. 10/2011 and amendments, conformity with the overall migration limit for simulants A, B, and D2 demonstrates suitability for contact with all kinds of foodstuffs. QMA samples are therefore suitable for contact with all kinds of foodstuffs up to 70°C for a maximum of 2 hours, or up to 100°C for a maximum of 15 minutes.

Bio-Safety Test

The purpose of this testing is to evaluate the biological suitability of the materials of construction for the applications in which the QMA cartridge is typically used.

Toxicity Test

The most commonly applicable methodologies are those specified in the United States Pharmacopeia (USP) under the Class VI Biological Tests for Plastics. QMA cartridges were submitted to NAMSA, an independent testing laboratory, for testing in accordance with current USP procedures. The test article was prepared at a ratio of 4 g : 20 mL, extracted at 250°F (121°C) for 1 hour, and subjected to the following studies to evaluate the potential for a local irritant or toxic response to material implanted in direct contact with muscle tissue:

1. USP Systemic Toxicity Study in the mouse.
2. USP Intracutaneous Toxicity Study in the rabbit.
3. USP Muscle Implantation Study in the rabbit.

Conclusion

The results of the tests conducted on the QMA filter cartridge indicate that it is non-toxic in all of the assays performed, satisfying the requirements for USP Plastics Class VI. Full copies of the test report are available upon request.

Summary of Qualification Results

The table below consolidates the key qualification outcomes for quick reference.

Qualification Test	Key Result / Rating
Filtration efficiency	99.98% — “Absolute” (Beta 5000) per ASTM F795-88
Core collapse (21°C)	Integral to 75 psid (5.2 bar)
Core collapse (80°C)	Integral to 30 psid (2.0 bar)
Steam sterilization	Up to 10 cycles at 275°F (135°C), 30 min/cycle
Autoclave	30 min at 250°F (121°C), no end load
Endotoxin	0.019 EU/mL; 5.7 EU/device (meets FDA & USP)
Non-volatile residue	1 mg (USP 661 limit ≤ 15 mg)
Food contact	Compliant, EU 1935/2004 & 10/2011
Bio-safety	Non-toxic — USP Class VI

Notes