QMA Qualification Guide

ISO 9001:2015

Preface

Each section of this Qualification Guide represents only the summary portion of the actual test. If your company has a need for expanded detail on any particular test method or the actual data, please contact Graver Technologies Liquid Filter Group for assistance at 800-249-1990.

Table of Contents

Preface	2
Table of Contents	3
Introduction	4
Nomenclature & Construction	5
Product Traceability	6
Flow Rate Test	6
Core Collapse (Differential Pressure Stress) Test	7
Sanitization/ Sterilization Test	8
Endotoxin Test	
Non-Volatile Residue	9
European Regulation No 1935/2004 and European Regulation 10/2011	10
Bio-safety Testing	11
Notes	12

Introduction

The Graver Technologies QMA pleated filter cartridges are designed as an exceptionally clean, non-leaching, non-shedding barrier for membrane filtration. These filters offer reliable performance in removing inert contaminants larger than their rated pore sizes. All QMA filter cartridges incorporate polypropylene melt blown media to provide filtration efficiency of 99.98% according to ASTM 795-88, *Standard Practice for Determining the Performance of Filter Medium Employing a Single Pass, Constant Rate Liquid Test*. In addition, the QMA cartridge components (cage, core, end caps and support layers) are entirely polypropylene, which conforms to both CFR for Indirect Food Additives and USP Class VI standards. The QMA filter cartridges can be sanitized with steam, hot water, or compatible chemicals. All the QMA filter products are fabricated in an ISO 9001, Rev. 2015 Registered manufacturing facility.

This report contains results of laboratory tests performed on Graver Technologies' QMA cartridge filters. This document describes:

- Flow Rate Testing
- Core Collapse (Differential Pressure Stress) Testing
- Sanitization and Sterilization Testing
- Endotoxin Test
- Extractable Testing (NVR)
- Bio-safety Testing

Nomenclature & Construction

QMA NOMENCLATURE INFORMATION										
Filter Type	Retention Rating (microns)		Nominal Length (inches)		End Configuration		Gasket or O-Ring		Options	
QMA Series	0.2	5	–5	–29.25[1]	P	Double Open End	B	Buna-N	–I	End Cap Insert for Steaming
	0.45	10	–9.75[1]	–30	P2	226/Flat Single Open End	E	EPDM		
	1	20	–10	–39[1]	P3	222/Flat Single Open End	S	Silicone	–R	Factory Pre-Rinse
	2.5		–19.5[1]	–40	P7	226/Fin Single Open End	T	Teflon encap. Viton (O-Rings only)[2]		
			–20		P8	222/Fin Single Open End				
					PX	Extended Core				
					AM	Single Open End, Internal O-Ring	T	Teflon Gasket		
Example: QMA 1–20P3V–R					NPC	Double Open End, Internal O-Ring	V	Viton		
QMA	1		–20		P3		V		–R	

Materials of Construction

Media:	Melt blown polypropylene – 7.0 ft^2 (0.65 m^2)
Drainage Layer:	Polypropylene
Core:	Polypropylene
Cage/Outer Sleeve:	Polypropylene
End Caps:	Polypropylene
O-Rings:	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 filter elements are produced and distributed according to a Quality Management System that is registered for compliance to EN ISO 9001:2015. All data concerning materials used and production data are documented, accessible and fully traceable.

Flow Rate Test

To contribute to the overall operating economics of an existing filter system, it is important that process filter cartridges offer high flow rates at low-pressure drops. For new systems, this can also allow a smaller filter housing to be used with a resultant savings 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 pressure of water can be regulated and was adjusted to 18 psi (1.2 bar).
3) The flow through the filter is adjusted to establish a test differential pressure across the filter of 1 psid.
4) The flow rate through the filter housing is recorded.
5) The test is repeated with several cartridges for each pore size.

Conclusions

Based on this testing, the typical flow rate/pressure drop characteristics of QMA cartridges per 10-inch cartridge length are:

0.2 µm:	2.83 gpm/PSID
0.45 µm:	4.50 gpm/PSID
1.0 µm:	5.24 gpm/PSID
2.5 µm:	5.88 gpm/PSID
5.0 µm:	9.47 gpm/PSID
10.0 µm:	12.05 gpm/PSID

Core Collapse (Differential Pressure Stress) Test

In normal use a filter cartridge will be exposed to an increasing differential pressure as the filter accumulates contaminants. In addition, due to normal stops and starts in a production line, the filter will be subjected to numerous differential pressure surges. The limiting factor in a filter cartridge's resistance to differential pressure is the strength of the cartridge core.

The testing regimen below was designed to stress the QMA filter core under more rigorous conditions than the filter would normally be exposed to in "real world" operation. To pass this test, the filter cartridge must remain integral throughout the pressure testing.

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 permeability of a test liquid.
2) The core is installed into the filter housing, which is attached to a hydraulic test system.
3) At ambient temperature, hydraulic pressure is slowly increased until the core collapses.
4) The temperature of the hydraulic fluid, and hence the housing/filter core, is increased to 176°F (80°C).
5) The hydraulic pressure is slowly increased until the core collapses.

Results

The filter cores consistently avoided collapse until well over 100 psid (6.9 bard) at ambient temperature (70°F/21°C). The filter cores consistently avoided collapse until well over 60 psid (4.1 bard) at an elevated temperature of 176°F (80°C).

Conclusion

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

Sanitization/Sterilization

Steam Sterilization Test

Under certain conditions it may be required to steam sterilize or sanitize the QMA cartridge to reduce the incidence of extraneous organisms that may come from the environment or may be filtered from the fluid being processed. Several procedures may be used on the QMA cartridge. This section outlines the test procedures, results and conclusions used in validating QMA cartridges for steam sterilization and hot water sanitization.

Test Procedure

1) A filter cartridge is installed into the test system, wetted with clean water, and integrity tested with the data recorded.
2) The filter system is connected to a source of clean, dry, saturated steam with a maximum pressure of 45 psid (3.1 psia).
3) The filter is steamed at a temperature of 275°F (135°C) and 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, 3, and 4 are repeated. After every third cycle the cartridge is re-wetted, and integrity tested.

Conclusion

Based on this testing, the QMA filter 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 thus is a viable option to the steam-in-place process. The QMA filter cartridges may therefore 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 (176°F/80°C) through the filter system for at least 30 minutes after the filter has reached a stable temperature. The time will be operating condition dependent and it should be validated for the user's specific system.

Steam sterilization of a filter system is far more rigorous than autoclave or hot water sanitization. Thus, it can be safely assumed that QMA filter cartridges can be autoclaved or hot water sanitized at least 10 times under the above specified conditions.

Endotoxin Test

Endotoxins are complex polysaccharide molecules (LPS) composed of lipid (lipid A) and polysaccharide sides chains and are integral components of the outer membrane of gram negative bacteria. These molecules are not secreted but are released only when the cells are disrupted or destroyed. Above certain levels, endotoxins elicit an antigenic response, resulting in fever and altered resistance to bacterial infections. Because of this sensitivity, it is important to monitor products which may contact fluids that could be administered to humans or animals.

The detection of endotoxins is accomplished using Limulus Amebocyte Lysate (LAL) Kinetic Chromogenic Assay. In this test, a filter element is extracted with non-pyrogenic Water for Injection (WFI). Endotoxin levels in the extracted fluid are then measured spectrophotometrically and compared to standard concentrations. These values are reported as EU/ml (Endotoxin Units/ml).

Results

NAMSA of Northwood Ohio conducted the testing on a sample of QMA. Levels were reported at 0.019 EU/ml and 5.7 EU/device. This level is well below the criteria established by the US FDA of 0.5 EU/ml and the USP requirement of 20 EU/device.

Non-Volatile Residue

The test is designed to measure the amount of impurities extracted from plastics when leached with extraction medium (purified water) over a specified period and temperature.

Results

NAMSA of Northwood Ohio conducted the testing on a sample of QMA. The upper limit for Physiochemical Test-Plastics under the current United States Phamacopeia (USP 661) is ≤ 15 mg based upon weight. The QMA yielded a value of 1 mg, indicating that there are no significant extractables noted for non-volatile residue and meeting the USP limits.

European Regulation No 1935/2004 and European Regulation 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 must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change or deterioration in the composition or properties of the food. Tests for migration behavior in direct food contact were conducted by Belgium Packaging Institute in a variety of liquids to simulate aqueous, acidic, alcoholic, and fatty foodstuffs.

Results

The test results indicate that the overall migration of all of the individual parts will not exceed the overall migration limit of 10 mg/dm^2 or 60 mg/kg foodstuffs for simulant A (10% ethanol, representing all aqueous foodstuffs), simulant B (3% acetic acid, representing all foodstuffs with a pH below 4.5) and simulant D2 (95% ethanol and isooctane instead of olive oil representing all fatty foodstuffs) using the given conditions. In accordance with the European 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. Consequently, QMA samples are suitable for contact with all kinds of foodstuffs up to 70 °C for maximum 2 hours or up to 100 °C for maximum 15 minutes.

Bio-safety Test

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

Toxicity Test

Some of the most common applicable test methodologies are those specified in The United States Pharmacopoeia, under Group VI Biological Tests for Plastics. The QMA cartridge filter was submitted to NAMSA, an outside testing laboratory for testing in accordance with current USP procedures.

Samples were evaluated for bio-compatibility in accordance with the guidelines of the current USP. The purpose of the study was to evaluate the potential for a local irritant or toxic response to material implanted in direct contact with muscle tissue. There are three tests to meet the requirements for USP Plastics Class VI. The test article was prepared at a ratio of 4g:20 ml and extracted at 250°F (121°C) for 1 hour and subjected to the following tests:

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

Based on this testing, the results of the tests conducted on the QMA filter cartridge indicate that it is non-toxic in any of the assays conducted. Full copies of the test report are available upon request.

Notes