TefTEC

Qualification Guide

ISO 9001:2015

Preface

Each section of this Validation 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.

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TefTEC Performance Qualification Guide

The Graver Technologies TefTEC PTFE Membrane pleated filter cartridge, available in 0.05µm, 0.1µm, 0.2µm, 0.45µm, and 1.0µm ratings, is designed as an exceptionally clean, non-leaching, non-shedding barrier for filtration. This hydrophobic filter offers reliable performance in removing both biological and inert contaminants larger than the rated pore size. All TefTEC filter cartridges incorporate ePTFE (expanded polytetrafluoroethylene) membrane. In addition, the TefTEC 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 Biological Test for Plastics standards. The TefTEC filter cartridges can be sanitized with steam, hot water, or compatible chemicals. Each filter is rinsed with 18 MΩ-cm de-ionized water and integrity tested before release from manufacturing. All TefTEC filter products are fabricated in an ISO 9001, Rev. 2015 Registered manufacturing facility.

This report contains results of laboratory tests performed on Graver Technologies' 0.05µm, 0.1µm, 0.2µm, 0.45µm, and 1.0µm TefTEC membrane cartridge filters and/or components.

Nomenclature & Construction

TefTEC NOMENCLATURE INFORMATION								
Filter Type	Retention Rating (microns)		Nominal Length (in)		End Configuration		Gasket or O-Ring		Options	
TefTEC Series	0.05	0.45	–5	–20	P	Double Open End	B	Buna-N	–W	Pre-Wet
	0.1	1	–9.75*	–30	P2	226/Flat Single Open End	E	EPDM		
	0.2		–10	–40	P3	222/Flat Single Open End	S	Silicone		
					P7	226/Fin Single Open End	T	Teflon encap. Viton (O-Rings only)		
					P8	222/Fin Single Open End				
					AM	Single Open End, Internal O-Ring	T	Teflon (gaskets)		
Example: TefTEC 0.1–20P2S–W					NPC	Double Open End, Internal O-Ring	V	Viton		
TefTEC	0.1		–20		P2		S		–W	

Materials of Construction

Membrane: Single layer expanded polytetrafluoroethylene (e-PTFE) – 8.6 ft^2 (0.79 m^2)
Drainage Layer: Polypropylene
Core: Polypropylene
Cage/Outer Sleeve: Polypropylene
End Caps: Polypropylene
O-Rings: Silicone (standard)
EPDM
Buna-N
Viton Teflon Encapsulated Viton

Product Traceability

TefTEC 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 TefTEC filters are non-destructively integrity tested and flushed with Purified Water with a maximum conductivity of 1.1 µS/cm @ 20°C (68°F) and a maximum TOC (Total Organic Carbon) content of 0.5 mg (500ppb) of carbon per liter. They are then dried using HEPA filtered air and sealed in a protective polyethylene bag within the cleanroom. To enable full traceability of all TefTEC filter products, each filter module is marked with an individual serial number, a lot number, product code and general description which is also shown on both the bag label and on the outer product box, therefore all data concerning materials used and production data are documented, accessible and fully traceable.

Cartridge Integrity Testing

Graver Technologies, as part of its quality process, integrity tests all TefTEC filter cartridges before release from manufacturing. The specific test used is a Diffusion Test. A discussion of this testing procedure is included in the package insert accompanying the TefTEC product. For an integral cartridge the air diffusion rate, which is a measure of the rate at which air diffuses through the water-filled pores of the membrane, must be below a specified value at the Integrity Test pressure. A cartridge with even a minor defect will exhibit much higher airflow rates when measured by this test.

Test Procedure

1) The filter cartridge is first wetted with a 60/40 IPA/de-ionized water mixture.
2) The completely wetted filter is then installed into the system and a pressure of 5 psid (0.34 bar) of compressed air is applied to the upstream side to remove any excess water in the housing, which passes through the filter and is drained from the downstream side of the housing.
3) The air pressure is increased to the value shown in the Table below, "Diffusion Pressure" and the system is allowed to stabilize for 2 minutes.
4) The diffusive air flow through the filter system is measured and the filter passes the integrity test only if the diffusion flow value is less than the "Maximum Diffusion" shown in the Table below.

Pore Size	Diffusion Test Pressure (psig)	Maximum Diffusion (cc/min) per 10-Inch Cartridge Length	Bubble Point
0.05 µm	22 (1.5 bar)	≤ 50	≥ 28 psid (1.9 bar)
0.1 µm	18 (1.24 bar)	≤ 50	≥ 22 psid (1.5 bar)
0.2 µm	12 (0.8 bar)	≤ 35	≥ 15 psid (1.0 bar)
0.45 µm	5 (0.34 bar)	≤ 15	≥ 6 psid (0.4 bar)
1.0 µm	3 (0.21 bar)	≤ 15	≥ 4 psid (0.27 bar)

Flow Rate Testing

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 – Liquid Flow

1) A filter cartridge is installed into the test system and wetted with 60/40 IPA/de-ionized water. An integrity test is performed and the results are recorded. (See Page 3 for Integrity Test Procedure.)
2) The filter system is connected to a source of clean water. The water pressure can be regulated and is adjusted to 18 psi.
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.

Results

All of the filter cartridges tested showed flow rates, summarized below, meeting the minimum specifications for that pore size.

0.05 µm		0.1 µm		0.2 µm		0.45 µm		1.0 µm	
Cart. ID #	Flow GPM at 1 PSID	Cart. ID #	Flow GPM at 1 PSID	Cart. ID #	Flow GPM at 1 PSID	Cart. ID #	Flow GPM at 1 PSID	Cart. ID #	Flow GPM at 1 PSID
1	2.8	2	3.8	3	4.5	4	7.7	5	10
Claimed Typical Clean Water Flow Rate	2.8 GPM/ psid	Claimed Typical Clean Water Flow Rate	3.8 GPM/ psid	Claimed Typical Clean Water Flow Rate	4.5 GPM/ psid	Claimed Typical Clean Water Flow Rate	7.0 GPM/ psid	Claimed Typical Clean Water Flow Rate	10 GPM/ psid

Conclusions

Based on this testing, the typical liquid flow rate/ pressure drop characteristic of TefTEC Cartridges per 10-inch cartridge length are:

0.05 µm: = 2.8 gpm/psid
0.1 µm: = 3.8 gpm/psid
0.2 µm: = 4.5 gpm/psid
0.45 µm: = 7.7 gpm/psid
1.0 µm: = 10 gpm/psid

Test Procedure – Clean Air Permeability (ISO12500-4)

1.) A filter cartridge is installed into the test system equipped with a regulated, filtered, compressed air supply at ambient temperature. Downstream valve permits controlling system pressure from zero (open to atmosphere to simulate vent) to in excess of 60 psig.

2.) Pressurize the system to the targeted air flow test level of 5, 15, 25, 35 and 50 SCFM under vent conditions (<10 psig) or 30 psig.
3.) After stabilization, measure and record the differential pressure at the corresponding airflow (SCFM).

Results

The five different pore sizes of TefTEC filters (10" increments) were tested and the air flow rates are summarized below.

	DP at Flows (m3/hr)				
	8.5	*25.5*	*42.5*	*59.5*	*85*
	DP at Flows (SCFM)				
	5	*10*	*25*	*35*	*50*
0.05 µm	**0.08**	**0.23**	**0.41**	**0.53**	**0.87**
0.1 µm	**0.09**	**0.24**	**0.37**	**0.56**	**0.85**
0.2 µm	**0.08**	**0.22**	**0.34**	**0.49**	**0.74**
0.45 µm	**0.04**	**0.09**	**0.19**	**0.25**	**0.35**
1.0 µm	**0.03**	**0.06**	**0.10**	**0.16**	**0.26**

Test Conditions: System pressure at <10 psig, 65° F (18°C), outlet open to atmosphere.

	DP at Flows (m3/hr)				
	8.5	*25.5*	*42.5*	*59.5*	*85*
	DP at Flows (SCFM)				
	5	*10*	*25*	*35*	*50*
0.05 µm	**0.05**	**0.15**	**0.25**	**0.35**	**0.57**
0.1 µm	**0.05**	**0.14**	**0.26**	**0.37**	**0.54**
0.2 µm	**0.05**	**0.13**	**0.22**	**0.33**	**0.45**
0.45 µm	**0.02**	**0.05**	**0.10**	**0.15**	**0.21**
1.0 µm	**0.02**	**0.03**	**0.06**	**0.10**	**0.13**

Test Conditions: System pressure at 30 psig, 65° F (18°C).

Core Collapse (Differential Pressure Stress) Testing

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 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 TefTEC 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 testing is repeated by increasing the temperature of the hydraulic fluid, and hence the housing/filter core, to 176°F and then slowly increasing the hydraulic pressure until the core collapses.

Results

The filter cores consistently avoided collapse until well over 100 psid at ambient temperature (70°F). The filter cores consistently avoided collapse until well over 60 psid at an elevated temperature of 176°F.

Conclusion

Based on this testing and Graver Technologies TefTEC cartridge fabrication methodology, TefTEC cartridge filters can withstand differential pressures up to 80 psid at 70°F, and 40 psid at 176°F and remain integral.

Steam Sterilization Testing

Under certain conditions it may be required to steam sterilize or sanitize the TefTEC 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 TefTEC cartridge. This section outlines the test procedures, results and, conclusions used in validating TefTEC cartridges for steam sterilization and hot water sanitization.

Test Procedure

1) A filter cartridge is installed into the test system, wetted with IPA/de-ionized 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 bar).
3) The filter is steamed at a temperature of 275°F (135°C) and a maximum differential pressure of 5 psid for 30 minutes. The cartridge is allowed to cool for 30 minutes and then the process is repeated.
4) After every 3 steaming cycles, the cartridge is integrity tested and compared against the maximum diffusion rate with results recorded as pass/fail.
5) Testing was performed on 0.1µm TefTEC filters.

Conclusion

Based on this testing, the TefTEC filter cartridges remain integral when steam sterilized up to 100 times at 135 °C for 30 minutes per cycle.

Hot Water Sanitization Testing

A convenient method of sanitizing the filter is to flow hot water (185 °F/ 85 °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.

Live steam sterilization of a filter system is far more rigorous than hot water sanitization. Thus, it can be safely assumed that TefTEC filter cartridges can be hot water sanitized at least 100 times under the above specified conditions.

Bacteria Challenge Testing

The PTFE media utilized in TefTEC cartridge filters has been tested for liquid bacterial retention and aerosol bacterial retention by independent laboratories. The test procedures were adapted from ASTM F838-05 Standard Test Method: "Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration". The test samples were challenged with a minimum of 1 x 10^7 CFU/cm^2 of effective filtration area, where CFU represents Colony Forming Units. Additionally, for the liquid bacterial retention testing, the bubble point of the media was tested prior to sterilization and after the challenge.

Results

The retention performance of the media can be expressed as Log Reduction Value (LRV). The LRV is defined as follows:

$$LRV = \text{Log}_{10} \frac{\text{Number of Organisms Challenged to the Filter}}{\text{Number of Organisms in the Effluent from the Filter}}$$

If no organism is detected in the filtrate, the number 1 is used in the denominator ($10^0 = 1$).

Bacteria Log Reduction Values:

Pore Size	Liquid Challenge with *Brevundimonas diminuta* ATCC # 19146	Liquid Challenge with *Serratia marcescens* ATCC# 14756	Aerosol Challenge with *Staphloccus aureus* ATCC# 6538	Aerosol Challenge with *Stapholoccus aureus* ATCC# 6538
0.2 µm	≥ 8.2			
0.45 µm		≥ 8.3	≥ 6.9	
1.0 µm				≥ 6.4

Conclusion

The PTFE media used in TefTEC cartridges has been demonstrated to be bacterially retentive with LRVs for appropriate challenge organisms more than sufficient to reduce bioburden to acceptable levels.

Bio-safety Testing

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

Toxicity Testing

Some of the most common applicable test methodologies are those specified in The United States Pharmacopoeia, under Group VI Biological Tests for Plastics. The TefTEC cartridge filter components have been tested by NAMSA, an outside testing laboratory 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 a USP plastic class VI. The test articles were 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 TefTEC cartridge filter components indicate that they are non-toxic in any of the assays conducted.

Purity/Effluent Cleanliness Testing:

Non-volatile Residue:

Non-Volatile Residue per USP Physicochemical Test is one of the tests used to characterize and compare new polymeric materials or to audit materials used in production. The test provides basic information about the presence and nature of water-soluble extractables. Test samples are extracted for 24 hours in purified water a 70°C and analyzed. A 50 ml aliquot of the eluate is evaporated to dryness and the weight of the residue is determined. The difference between the sample and the blank may not exceed 15mg.

Oxidizables:

The oxidizable substances procedure is an indirect measurement of organic material which may extract into the filtrate. It is adapted from the USP standard for purified water. The sample is acidified, and potassium permanganate is added. If all of the pink color does not disappear (not all of the potassium permanganate being reduced by oxidizable substances in the extract) the sample passes the test.

Cytotoxicity:

The cytyotoxicity test is adapted from the MEM Elution test as described in USP by sharing the extract from a single extraction for all the requested tests (Pyrogen, cytotox, non-volatile residue, oxidizable substances, Heavy Metals, and total organic carbon). An aliquot of the extract is mixed with serum-supplemented mammalian cell culture media (MEM) and incubated in contact with a mono-layer of L-929 cells (mouse fibroblasts) at 37°C. After 48 hours the cells are scored for cytopathic effects.

Endotoxin:

The Limulus Amebocyte Lysate (LAL) test is an in vitro assay for detection and quantification of bacterial endotoxin. The test is based upon the reactivity of bacterial endotoxins with a lysate derived from the circulating cells of the horseshoe crab (limulus Polyphemus). The LAL test is an acceptable alternative to the USP rabbit pyrogen test although the test is simple; end-point reactions with proper controls and inhibition and enhancement tests are included.

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.

Notes