Graver Technologies

TefTEC V
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.

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TefTEC V Performance Qualification Guide

The Graver Technologies TefTEC V Pleated filter series is a 0.2µm PTFE cartridge designed as an economical, non-leaching, non-shedding barrier for vent and plant gas filtration. This hydrophobic filter offers reliable performance in removing both biological and inert contaminants larger than the rated pore size. All TefTEC V filter cartridges incorporate an ePTFE (expanded polytetrafluoroethylene) membrane with components (cage, core, end caps and support layers) composed entirely of polypropylene which conforms to both CFR for Indirect Food Additives and USP Class VI Biological Test for Plastics standards. The TefTEC V 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 V filter products are fabricated in an ISO 9001, Rev. 2015 Registered manufacturing facility.

This report contains results of laboratory tests performed on Graver Technologies' 0.2µm TefTEC V membrane cartridge filters and/or components.

Nomenclature & Construction

TefTEC V NOMENCLATURE INFORMATION						
Filter Type	**Retention Rating** (microns)	**Nominal Length** (inches)		**End Configuration**		**Gasket or O-Ring**
TefTEC V Series	0.2	–5	–20	P	Double Open End	B Buna-N
		–9.75*	–30	P2	226/Flat Single Open End	E EPDM
		–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	T Teflon (gaskets)
				AM	Single Open End, Internal O-Ring	V Viton
Example: TefTEC V 0.2–20P2S				NPC	Double Open End, Internal O-Ring	
TefTEC V	0.2	–20		P2		S

Materials of Construction

Membrane:	Single layer expanded polytetrafluoroethylene (e-PTFE) – 6.8 ft^2 (0.63 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 V 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 V 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 V 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 V 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 V 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.

Diffusion 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 9 PSIG (620 mbar), and the system is allowed to stabilize for 2 minutes.
4) The diffusive air flow through the filter system is recorded.

Lot #	Serial #	Diffusive Flow (cc/min)
2252016	1	16.6
	2	12.5
22101551-0104	1	7.08
	2	7.78
	5	6.23
	6	5.23
90800	38	8.56
	42	6.2
		8.8

Specification

The average value reported for the multiple cartridge lots built is 8.8 cc/min, ranging from a high of 16.6 cc/min to a low off 5.23 ml/min, which falls well within the targeted goal of ≤ 30 cc/min.

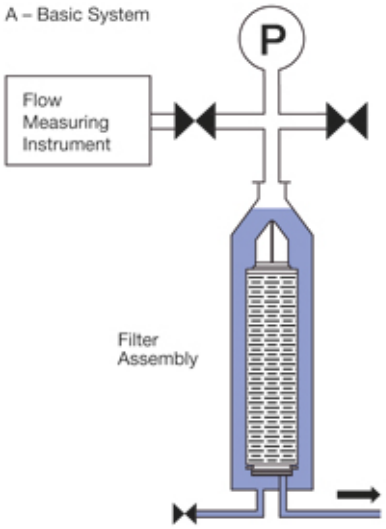
Pore Size	Diffusion Test Pressure psig (mbar)	Maximum Diffusion (cc/min) per 10-Inch Cartridge Length	Bubble Point psig (mbar)
0.2 µm	9 (620)	≤ 30	12 (820)

Cartridge Integrity Testing

Water Intrusion Test

Traditional integrity test methods for PTFE membrane filters, such as the Diffusion Flow test and the Bubble Point test, require that the filter membrane is fully wetted, requiring the use of an organic solvent, typically isopropyl alcohol (IPA). Use of these solvents imposes certain constraints which must be taken into consideration as well as leaves the PTFE membrane in a wet state, which is unsuitable for immediate use as a vent filter. The Water Intrusion Test (WIT) eliminates the requirement for solvent pre-wetting and thus allows the filter to be utilized without additional processing steps.

In this procedure, pressurized water is utilized as the test medium as opposed to pressurized air. Since PTFE is a hydrophobic membrane, the water should not freely pass through the membrane at a significant rate. When the pressurized water is drained from the housing, the membrane would not be wet-out and thus can be immediately utilized.



Water Intrusion Test Procedure

1) The dry filter, which was previously tested by Diffusion Flow, is installed into the filter housing which is then filled with deionized water.
2) An automated integrity test device is utilized to pressurize the water to 36 PSIG (2500 mbar). After 5 minutes stabilization period, the volume of water passing through the filter is measured for 1 minute and reported.
3) The pressure is vented from the vessel, the water is drained, and the filter is ready for use.

Serial #	Test Pressure PSIG (mbar)	Flow Rate (ml/min)
38	36 (2500)	0.59
42		0.46
2		0.31
21		0.36
32		0.48
40		0.31
		0.42

Specification

The average value derived from the cartridges tested was 0.42 ml/min. This corresponds with an average Diffusion Test value of 8.8 cc/min which is within the targeted specification of 0.75 ml/min.

Pore Size	WIT Test Pressure psig (mbar)	Maximum Water flow (ml/min) per 10-Inch Cartridge Length
0.2 µm	36 (2500)	≤ 0.75

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 (1.24 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.

Results

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

Flowrate (GPM)	TefTEC V Flux (GPM/PSID/10")					
3	2.72	3.06	2.44	3.06	3.26	2.82
5	2.40	2.72	2.26	2.55	2.95	2.48
7	2.28	2.59	2.11	2.48	2.83	2.37
10	2.09	2.33	1.94	2.20	2.52	2.14
	2.37	**2.67**	**2.19**	**2.57**	**2.89**	**2.45**

Specification

Based on this testing, the typical liquid flow rate/ pressure drop characteristic of TefTEC V Cartridges per 10-inch cartridge length is 2.52 gpm/psid (13.8 LPM/100 mbar).

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. The downstream valve permits controlling system pressure from zero (open to atmosphere to simulate vent) to in excess of 60 psig (4.1 bar).
2.) Pressurize the system to the targeted air flow test level of 5, 15, 25, 35 and 50 SCFM under vent conditions of <10 psig (0.69 bar) or 30 psig (2.0 bar).
3.) After stabilization, measure and record the differential pressure at the corresponding airflow (SCFM).

Results

TefTEC V filters (10" increments) were tested and the air flow rates are summarized below.

System Pressure <10 psig (vent)	Flow (SCFM) vs Pressure Drop				
Sample ID	**5**	**15**	**25**	**35**	**50**
TefTEC V 0.2 ("H_2O)	2.9	8.1	13.2	18.1	25.3
TefTEC V 0.2 (PSID)	0.07	0.29	0.48	0.65	0.91

System Pressure 30 psig	Flow (SCFM) vs Pressure Drop				
Sample ID	**5**	**15**	**25**	**35**	**50**
TefTEC V 0.2 ("H_2O)	1.6	5.1	8.9	12.8	18.9
TefTEC V 0.2 (PSID)	0.06	0.18	0.32	0.46	0.68

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 V 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 (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).

Specification

Based on this testing and Graver Technologies TefTEC V cartridge fabrication methodology, TefTEC V cartridge filters can withstand differential pressures up to 80 psid (5.5 bard) at 70°F (21°C), and 40 psid (2.75 bard) at 176°F (80°C) and remain integral.

Steam Sterilization Testing

Under certain conditions it may be required to steam sterilize or sanitize the TefTEC V 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 V cartridge. This section outlines the test procedures, results and, conclusions used in validating TefTEC V 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 bard).
3) The filter is steamed at a temperature of 275°F (135°C) and a maximum differential pressure of 5 psid (0.34 bard) 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 for each micron rating with results recorded as pass/fail.

Specification

Based on this testing, the TefTEC V filter cartridges remain integral when steam sterilized up to 50 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 V filter cartridges can be hot water sanitized at least 35 times under the above specified conditions.

Bacteria Challenge Testing

TefTEC V cartridge filters have been tested for aerosol bacterial retention. The test procedure was adapted from ASTM F2101 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials using a high level of an aerosol of Brevundimonas diminuta, having a mean particle size of 3.0 ± 0.3 microns. The test samples were challenged with a minimum of 1 x 10^7 CFU (Colony Forming Units) per cartridge.

Results

The retention performance of the media can be expressed as Log Reduction Value (LRV) or as a percentage (BFE – Bacterial Filtration Efficiency).

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

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

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Challenge Level
T = Total CFU recovered downstream of the test article

Bacteria Log Reduction Values:

Sample	Total CFU Recovered	Filtration Efficiency	LRV
1	<3[a]	99.999988	>6.9
2	<3[a]	99.999988	>6.9
3	<3[a]	99.9999934	>7.2
4	<3[a]	99.9999934	>7.2
5	<3[a]	99.9999949	>7.3
6	<3[a]	99.9999949	>7.3

a - There were no detectable colonies on the filter

Conclusion

The TefTEC V cartridges which have been determined to meet integrity test requirements (Diffusion Flow) have demonstrated to be sufficiently retentive for aerosolized bacteria 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 V 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 V 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 V cartridge filter components indicate that they are non-toxic in any of the assays conducted.

NOTES