3M Purification Inc.

LifeASSURE™ PFS Series PTFE Filter Validation Guide

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I. Introduction

This Guide contains validation data and regulatory support information pertinent to the 3M Purification Inc. LifeASSURE™ PFS Series PTFE filters. It contains information that supports the safety, efficacy and regulatory compliance of filters in pharmaceutical, biological and bio-processing filtration applications.

LifeASSURE PFS series PTFE filters are used in critical process stages where microbial-rated filtration is required. LifeASSURE PFS series PTFE filters meet the FDA's definition of a sterilizing grade filter as described in the Food and Drug Administration (FDA) Guideline on Sterile Drug Products Produced by Aseptic Processing, (June 1987). LifeASSURE PFS series PTFE filters are qualified for quantitative retention of *Brevundimonas diminuta (B. diminuta)* at a minimum challenge of 10^7 organisms/cm^2 of effective filter surface area. Bacteria challenge studies were conducted in accordance with ASTM method F838-05.

This Validation Guide has been prepared specifically for manufacturers requiring product documentation as part of their process validation. It includes the following information to support published performance claims:

- Cartridge construction
- Part Numbering System
- *B. diminuta* retention and correlation to non destructive integrity testing
- Air flow vs. differential pressure at atmospheric and elevated pressures
- Thermal stress — repeat steam cycles, repeat autoclave cycles
- Total Non-Volatile Gravimetric Extractables
- Effluent cleanliness
- Limulus Amebocyte Lysate (LAL) Testing
- Oxidizable Substance Testing
- United States Pharmacopoeia (USP) Biological Test for Plastics — Class VI and Elution Test Results

In addition to product performance test results, the following safety and regulatory support information is provided:

- ISO 9001:2008 Certification
- Certificate of Quality
- Drug Master File Number 16232
- Material Safety Data Sheets

LifeASSURE PFS series PTFE filters are manufactured and tested in accordance with procedures documented in 3M Purification Inc.'s Drug Master File (DMF) No.16232 on record with the U.S. Food and Drug Administration. Further technical data and product information can be found in LifeASSURE PFS series PTFE filter literature (70-0201-8715-2).

3M Purification would be pleased to supply you with any additional information you require. Further information may be obtained by contacting: 3M Purification Inc. Scientific Applications Support Services (SASS) at:

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Meriden, CT 06450 U.S.A.
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II. Cartridge Construction

Membrane: LifeASSURE™ PFS Series PTFE filters are made with a hydrophobic PTFE membrane.

Membrane inner and outer support layers: LifeASSURE PFS series PTFE membrane is pleated with a layer of polypropylene non-woven upstream support, and another layer downstream, providing upstream access of influent fluid and downstream flow of effluent fluid. Airflow is further enhanced by use of a second, polypropylene downstream flow distribution layer.

Cartridge hardware components: Inner core and outer cage are molded polypropylene. End cap adapters and plastic O-ring adapters are also polypropylene and contain a 316 stainless steel ring for dimensional stability. All cartridge filter components are assembled by thermal bonding.

Capsule hardware components: Capsule housing, vent valve, and drain valve are molded polypropylene. Vent and drain O-ring seals are available in various option elastomers.

Further details concerning LifeASSURE PFS series PTFE filters specifications and operating conditions are provided as follows:

Table 1. LifeASSURE™ PFS Series PTFE filter Materials of Construction.

Filter Configuration	Cartridge	Mini Cartridge		Capsule**				
	5" to 40"	2.5"	5"	2.5"	5"	10"	20"	30"
Membrane	PTFE							
Membrane Support Layer	Polypropylene							
Inner core, outer cage, capsule shell, end cap adapters and adapters	Polypropylene							
Adapter Reinforcing Ring	Stainless Steel	NA						
Filtration Surface Area: ft^2 (m^2)	11 (1.02)*	1.8 (0.17)	3.7 (0.34)	2.8 (0.26)	5.5 (0.51)	11 (1.02)	22 (2.04)	33 (3.07)

* per 10" element

** not for continuous compressed gas service.

III. Part Number Description

The table below provides the part numbering system for LifeASSURE PFS series PTFE filters.

Table 2. LifeASSURE™ PFS Series PTFE Filter Part Numbering System.

Cartridges

Grade Designation	Configuration	Height (Inches)	End Modification	O-ring Material
PFS020	A	**01** - 10 **02** - 20 **03** - 30 **04** - 40 **50** - 5	**B** - 226 O-ring & spear **C** - 222 O-ring & spear **F** - 222 O-ring & flat cap **J** - 226 O-ring & flat cap	**A** - Silicone **B** - Fluorocarbon **C** - EPR **D** - Nitrile **K** - PTFE Encapsulated fluorocarbon

Capsules

Grade Designation	Configuration	Height (Inches)	End Modification	Vent/Drain O-ring Material	Package Quantity
PFS020	J	**01** - 10 **02** - 20 **03** - 30 **25** - 2.5 **50** - 5	**A** - Sanitary fitting	**A** - Silicone **B** - Fluorocarbon **C** - EPR	**01** - 1 pack

Mini-Cartridges

Grade Designation	Configuration	Height (Inches)	End Modification	Package Quantity
PFS020	R	**01** - 2.5 **02** - 5	AN	**06** - 6 pack

IV. Product Operating Parameters

The table below provides operating parameters and specifications for LifeASSURE™ PFS series PTFE filters.

Table 3. LifeASSURE™ PFS Series PTFE Filter Operating Parameters and Specifications.

Filter Configuration	Cartridge	Mini Cartridge		Capsule*				
	5" to 40"	2.5"	5"	2.5"	5"	10"	20"	30"
Filter Rating	0.2 µm							
Maximum Differential Pressure								
Forward Pressure	80 psid (5.5 bar) @ 77 °F (25 °C) 25 psid (1.7 bar) @ 176 °F (80 °C)			75 psid (5.2 bar) @ 104 °F (40 °C)				
Reverse Pressure	65 psid (4.5 bar) @ 77 °F (25 °C)			65 psid (4.5 bar) @ 77 °F (25 °C)				
Maximum Operating Temperature	176 °F (80 °C)			104 °F (40 °C)				
Integrity Test Parameters - Forward Flow Test - @ 16 psig (1.1 bar)**								
25%/75% (v/v) TBA/Water @ 20 °C and 1 atm: cc/min.	≤ 8.7 *	≤ 1.4	≤ 2.9	≤ 2.2	≤ 4.4	≤ 8.7	≤ 17.4	≤ 26.1
60%/40% (v/v) IPA/Water @ 25 °C and 1 atm: cc/min.	≤ 35.5*	≤ 5.8	≤ 11.9	≤ 9.0	≤ 17.8	≤ 35.5	≤ 71.0	≤ 106.5
70%/30% (v/v) IPA/Water @ 25 °C and 1 atm: cc/min.	≤ 54.0*	≤ 8.8	≤ 18.2	≤ 13.7	≤ 27.0	≤ 54.0	≤ 108.0	≤ 162.0
Minimum Bubble Point: psig (bar)***	16 (1.1)							
Water Intrusion Test — Maximum Allowable Flow at 40 psig (2.76 bar) @ 20 °C and 1 atm: cc/min.	0.59	0.10	0.20	0.15	0.30	0.59	1.18	1.77
Autoclave Conditions:	Up to 259 °F (126 °C)							
In situ Steam Conditions:	Up to 293 °F (145 °C)			Do not *in situ* steam				

* not for continuous compressed gas service.

** **NOTE:** Wetting fluid should be maintained within +/- 2% v/v concentration and +/- 2 °C temperature.

*** Wet with 25%/75% (v/v) TBA/Water, 60%/40% (v/v) IPA/Water, or 70%/30% (v/v) IPA/Water.

V. Performance

A. Validation of Bacteria Retention and Correlation with Non-Destructive Integrity Tests

The validation of *B. diminuta* (ATCC 19146) retention for LifeASSURE PFS Series PTFE filters was performed in accordance with American Society of Testing and Materials (ASTM) method F838-05. Using this test methodology, LifeASSURE PFS series PTFE filters completely retained in excess of 1 x 10^7 CFU of *B. diminuta* per cm^2 of effective filter surface area.

The correlation between a non-destructive integrity test and assurance of microorganism retention is critical for filters used in sterile filtration applications. The LifeASSURE PFS series PTFE filter validation study establishes the relationship between non-destructive integrity tests and bacteria retention and serves as the basis for establishing pre- and post-use integrity testing of production filters.

In pharmaceutical manufacturing, integrity testing is recommended before and after the filtration process to ensure filter integrity. Correlation of the Forward Flow Integrity Test (25%/75% [v/v] TBA/Water wet) with Bacteria Retention:

Method:

LifeASSURE PFS series PTFE filters were taken from multiple production lots and steamed a minimum of five cycles. Cartridges were subjected to a forward flow integrity test and then challenge tested with *B. diminuta* in accordance with ASTM F838-05 to challenge levels in excess of 1 x 10^7 CFU/cm^2.

Each 10" cartridge was initially wetted with a 10 minute static soak of 25% tertiary butyl alcohol/75% water (v/v). Cartridges were then subjected to a forward flow integrity test using 16 psig of clean air. Forward flow rate (cc/min) at 20 °C and 1 atmosphere (1 atm) pressure in the forward flow direction was determined after allowing flow to stabilize. Cartridges were flushed to remove the residual alcohol prior to liquid challenge testing. Liquid challenge testing was then conducted using *B. diminuta* at challenge levels exceeding 1 x 10^7 CFU/cm^2 of filter area using ASTM methodology.

Results:

The test results shown in Table 4 demonstrate the correlation between the non-destructive Forward Flow Integrity Test and the complete retention of *B. diminuta*. LifeASSURE™ PFS series PTFE filters with forward flow integrity values of less than or equal to 10.3 cc/min successfully passed the bacterial challenge validation test. A limit of 8.7 cc/min was established for routine integrity testing. Thus, any 25% tertiary butyl alcohol/75% water (v/v) wetted LifeASSURE PFS series PTFE cartridge filter yielding a forward flow integrity value of less than or equal to 8.7 cc/min per 10" element at a 16 psi test pressure can be used with confidence.

Table 4. Correlation Test Results of the Forward Flow Integrity Test (25%/75% TBA/Water wet) with *B. diminuta* Retention for LifeASSURE™ PFS Series 10" PTFE Cartridge Filters.

Serial Numbers	Forward Flow Integrity @ 20 °C in 25%TBA/75% H_2O (v/v) @ 16 psi (cc/min)	Sterile Effluent
02T003-0005	4.4	Yes
02T003-0013	4.6	Yes
02T003-0007, 02T003-0011	4.7	Yes
02T003-0023	5.0	Yes
02T008-0013	5.2	Yes
02T003-0001, 02T008-0033, 02T008-0004	5.6	Yes
02T003-0022, 02T008-0035	5.7	Yes
02T008-0040, 02T008-0008, 02T008-0007	5.8	Yes
02T003-0024, 02T008-0032, 02T008-0006	5.9	Yes
02T009-0010	6.2	Yes
02T009-0027	6.3	Yes
02T003-0012, 02T009-0022, 02T009-0001	6.7	Yes
02T009-0007	6.8	Yes
02T008-0031	6.9	Yes
02T003-0018	7.5	Yes
02T011-0015	7.9	Yes
02T011-0001	8.1	Yes
02T011-0029	9.5	Yes
02T011-0003	10.3	Yes
02T009-0009	10.5	No
02T011-0011	10.7	Yes
02T008-0037	12.7	No
02T009-0016	13.1	No
02T009-0011	13.9	No
02T008-0046	15.3	No
02T003-0008	16.3	No
02T011-0009	16.7	No
02T011-0019	18.2	Yes
02T011-0025	19.1	Yes
02T011-0007	20.3	No
02T003-0006	21.3	No
02T011-0013	21.8	Yes
02T008-0044	26.9	No
02T008-0016	45.0	No
02T008-0027	77.3	No

B. Correlation of the 25%/75% TBA/H_2O Forward Flow Integrity Test with 60%/40% IPA/H_2O and 70%/30% IPA/H_2O:

Method:

LifeASSURE™ PFS Series PTFE filters are constructed with a hydrophobic PTFE membrane that requires a low surface tension fluid to thoroughly wet the membrane prior to performing an integrity test. 25%/75% TBA/H_2O (v/v) at a temperature of 20 °C was used as the wetting fluid to measure the forward flow of production cartridges prior to bacteria challenge. The correlation of 25%/75% TBA/H_2O forward flow integrity test results with *B. diminuta* retention and establishment of integrity test limits is shown in Table 4. Other wetting fluids such as 60%/40% IPA/H_2O or 70%/30% IPA/H_2O (v/v) can also be used for integrity testing. In order to establish integrity test limits for these fluids, a correlation to the limits determined for 25%/75% TBA/H_2O can be determined by obtaining the ratio of the forward flow integrity test values between these fluids. The ratio of test values between two fluids is dependent on the diffusion constant and the solubility coefficient of the test gas in these fluids[1].

Forward flow integrity tests were performed on a series of 10" LifeASSURE PFS series PTFE cartridge filters from three different production lots. Filter integrity test results were generated using 60%/40% IPA/H_2O and 70%/30% IPA/H_2O as the wetting fluid and compared to the same cartridges wet with 25%/75% TBA/H_2O. The membrane bubble point variation for the membrane wet with the three fluids was not significant, therefore all forward flow testing was conducted at 16 psi independently of the wetting fluid. A ratio was calculated between the integrity test values obtained with these wetting fluids and the integrity test values obtained with 25%/75% TBA/H_2O. The ratio was then used to calculate the maximum forward flow integrity test specification for each wetting solution based on the forward flow specification for the cartridge wet in 25%/75% TBA/H_2O. The IPA/H_2O based forward flow integrity test specifications for each wetting solution can be related to the bacterial retention correlation results of the product integrity tested when wet with 25%/75% TBA/H_2O (see Table 4 on previous page).

Results:

The results presented in Table 5 on the following page are the forward flow integrity measurements and averages for three production lots of 10" LifeASSURE PFS series PTFE cartridge filters wet in 25%/75% TBA/H_2O, 60%/40% IPA/H_2O, and 70%/30% IPA/H_2O. The forward flow integrity test limits for a 10" LifeASSURE PFS series PTFE cartridge filter can then be calculated by the equation:

$$DFL_{IPA} = DFL^{*}_{TBA} (DF_{AVG\ IPA}/DF_{AVG\ TBA})$$

Where: DFL_{IPA} = IPA-wetted Diffusive Flow Limit
DFL_{TBA} = TBA-wetted Diffusive Flow Limit = 8.7 cc/min for 10" LifeASSURE PFS series PTFE cartridge filter.
$DF_{AVG\ IPA}$ = Average IPA-wetted Diffusive Flow
$DF_{AVG\ TBA}$ = Average TBA-wetted Diffusive Flow

$DFL_{60/40\ IPA/H_2O}$ = (8.7)* (25.7/6.3) = 35.5 cc/min

$DFL_{70/30\ IPA/H_2O}$ = (8.7)* (39.1/6.3) = 54.0 cc/min

Therefore the forward flow specification for 10" LifeASSURE PFS series PTFE cartridge filters wet with 60%/40% IPA/H_2O is 35.5 cc/min and 54.0 cc/min for 10" cartridges wet with 70%30%/IPA/H_2O (v/v).

These 60%/40% IPA/H_2O and 70%/30% IPA/H_2O integrity test specifications can be used for 10" cartridges and capsules. Integrity test specifications for devices of different sizes have been normalized for appropriate effective filtration area and are specified in Table 3 on page 5. Wetting fluid concentrations and temperatures should be maintained within +/- 2% v/v concentrationand +/- 2 °C.

1. PDA Technical Report No.26 "Sterilizing Filtration of Liquids," PDA Journal of Pharmaceutical Science and Technology, 52, S1 (1998).

Table 5. Correlation of the 25%/75% TBA/H_2O Forward Flow Integrity Test with 60%/40% IPA/H_2O and 70%/30% IPA/H_2O Wetting Fluids for LifeASSURE™ PFS Series 10" PTFE Cartridge Filters.

Lot #	Serial #	25%/75% TBA/H_2O @ 16 psi & 20 °C (cc/min)	60%/40% IPA/H_2O @ 16 psi & 25 °C (cc/min)	70%/30% IPA/H_2O @ 16 psi & 25 °C (cc/min)
02T003	0089	6.3	25.4	39.4
02T003	0090	6.7	29.3	43.4
02T003	0091	6.5	26.9	40.7
02T003	0094	6.1	22.2	33.9
02T003	0097	6.4	27.4	39.4
02T003	0098	6.2	28.7	42.6
02T003	0099	6.8	27.8	48.0
02T003	0100	7.3	31.4	48.1
02T008	0010	5.8	22.7	33.9
02T008	0017	5.2	21.1	33.5
02T008	0022	5.6	20.5	33.6
02T008	0029	5.9	22.6	33.8
02T008	0043	6.4	22.8	33.6
02T008	0045	6.3	25.4	37.2
03T020	0767	6.3	25.3	40.6
03T020	0775	6.2	23.0	37.2
03T020	0778	6.3	25.3	36.9
03T020	0792	7.0	26.6	40.3
03T020	0793	6.5	26.1	39.5
03T020	0804	6.2	25.3	38.1
03T020	0807	6.4	26.5	40.1
03T020	0818	6.5	26.3	41.3
03T020	0826	6.4	25.4	35.7
03T020	0827	6.4	25.5	41.9
03T020	0829	6.1	25.3	37.3
03T020	0830	6.5	27.1	40.2
03T020	0831	6.5	27.1	39.8
03T020	0834	6.5	27.7	40.8
03T020	0835	6.5	27.2	42.1
03T020	0842	6.4	27.1	39.9
	Average	**6.3**	**25.7**	**39.1**

C. Correlation of the Water Intrusion Integrity Test (WIT) with Bacteria Retention:

Method:

LifeASSURE™ PFS Series PTFE cartridge filters were taken from multiple production lots and steamed a minimum of five cycles. Cartridges were subjected to a water intrusion integrity test and then challenge tested with *B. diminuta* in accordance with ASTM F838-05 to challenge levels in excess of 1 x 10^7 CFU/cm^2.

Each fully dry 10" cartridge was installed into a filter housing that was then filled with 20 ˚C water on the upstream side of the cartridge filter. The filter assembly was then subjected to a water intrusion integrity test at 40 psig. The water intrusion value (ml/min) was determined using a CUNOCheck™ 2 automated integrity test instrument. Cartridges were then wetted with alcohol and flushed to remove residual alcohol prior to liquid challenge testing. Liquid challenge testing was then conducted using *B. diminuta* at challenge levels exceeding 1 x 10^7 CFU/cm^2 of filter area using ASTM methodology.

Results:

The test results shown in Table 6 on the following page demonstrate the correlation between the Non-Destructive Water Intrusion Integrity Test and the complete retention of *B. diminuta*. LifeASSURE PFS series PTFE cartridge filters with water intrusion values of less than or equal to 0.60 ml/min successfully passed the bacterial challenge validation test. A limit of 0.59 ml/min was established for routine integrity testing. Thus, any LifeASSURE PFS series PTFE filter yielding a water intrusion value of less than or equal to 0.59 ml/min per 10" element at a 40 psig test pressure can be used with confidence.

Table 6. Correlation Test Results of the Water Intrusion Integrity Test (WIT) with *B. diminuta* Retention for LifeASSURE™ PFS Series 10" PTFE Cartridge Filters.

Serial Number	WIT @ 40 psig (2.8 bar) @ 20 °C & 1 atm (cc/min)	Sterile Effluent
02T003-0005	0.3	Yes
02T003-0024	0.3	Yes
02T003-0022	0.3	Yes
02T003-0012	0.4	Yes
02T003-0018	0.4	Yes
02T008-0040	0.4	Yes
02T003-0013	0.4	Yes
02T009-0022	0.4	Yes
02T008-0032	0.4	Yes
02T009-0010	0.4	Yes
02T003-0001	0.4	Yes
02T003-0007	0.4	Yes
02T003-0011	0.4	Yes
02T008-0033	0.4	Yes
02T008-0035	0.4	Yes
02T009-0027	0.4	Yes
02T008-0004	0.4	Yes
02T003-0023	0.4	Yes
02T008-0008	0.4	Yes
02T008-0006	0.4	Yes
02T009-0001	0.4	Yes
02T009-0007	0.5	Yes
02T008-0013	0.5	Yes
02T008-0031	0.5	Yes
02T008-0007	0.5	Yes
02T011-0015	0.5	Yes
02T011-0001	0.5	Yes
02T011-0029	0.6	Yes
02T011-0003	0.6	Yes
02T011-0011	0.6	Yes
02T003-0008	0.6	No
02T009-0016	0.6	No
02T009-0009	0.7	No
02T008-0046	0.7	No
02T011-0013	0.8	Yes
02T008-0037	0.8	No
02T011-0019	0.8	Yes
02T011-0009	0.8	No
02T011-0025	0.8	Yes
02T011-0007	0.9	No
02T009-0011	0.9	No
02T008-0044	0.9	No
02T003-0006	1.3	No
02T008-0016	1.4	No
02T008-0027	2.3	No

D. Demonstration of Aerosol Bacteriophage Virus Retention

The demonstration of bacteriophage ΦX-174 (ATCC 13706-B1) retention for LifeASSURE™ PFS Series PTFE cartridge filters was performed using an aerosolized challenge suspension of virus particles. An aerosol suspension of particles represents a typical challenge air filters receive as vent filters or in compressed gas filtration service.

Method:

A bacterial culture of Esherichia coli (*E. coli*) (ATCC 13706) at a concentration of 2 x 10^8–4 x 10^8 colony forming units (CFU) per mL was inoculated with the bacteriophage ΦX-174 stock culture (ATCC 13706-B1). Following incubation and complete *E. coli* lysis, the ΦX-174 phage culture was centrifuged and filtered through a sterilizing grade 0.2 µm filter. The stock culture of ΦX-174 was kept at 2 ºC–8 ºC.

The test filters were steam sterilized at 121º C for 1 hour. After the filter cooled to room temperature, the filter was placed into the test apparatus and the challenge aerosol initiated.

The challenge was delivered and sampling through an all glass liquid impinger (AGLI) was conducted to ensure clearance of residual aerosol from the chamber. Control runs (no filter in the test assembly) were performed before the test samples to determine the number of viral particles being generated in the challenge aerosol. A post challenge forward flow integrity test was performed on each cartridge filter at test pressure of 16 psig (1.1 bar). All cartridges were found to be integral.

The challenge suspension was delivered through a Chicago nebulizer using a peristaltic pump. The concentration was adjusted to provide a consistent challenge of > 1 x 10^8 plaque forming units (PFU) per test sample. The aerosol droplets were generated in a glass aerosol chamber and drawn into four all-glass liquid impingers (AGLI) in parallel. Each AGLI contained 30 mL aliquots of sterile peptone water (PEPW) to collect the aerosol droplets. The total air flow through the test filter was maintained at 140 liters per minute (LPM). Four AGLIs were connected in parallel to sample the effluent air at a flow rate of 48 LPM.

The AGLI fluid was assayed by placing 4 mL aliquots of each sample into tubes containing 2 mL of soft “top agar” and 2-3 drops of *E. coli* culture. The contents were mixed and poured over the surface of “bottom agar” plates. Plates were incubated at 37º C ± 2º C for 6–18 hours.

The Viral Filtration Efficiencies (VFE) were calculated using the following equation:

$$\text{VFE \%} = \frac{(\text{average plaques [control]} - \text{plaques [filter effluent]}) \times 100}{\text{average plaques [control]}}$$

Filters were flushed twice with 4 liters 60%/40% (v/v) isopropyl alcohol/water. An air pressure of 16 psig (1.1 bar) was applied and the forward flow rate was determined after 5 minutes stabilization.

Results:

One third of the effluent air was collected for quantification during testing; therefore, the plaque assay results for the controls and samples were converted to reflect the entire quantity of air passing through the test filter. The challenge level and filtration efficiencies of the samples are summarized in Tables 7 and 8.

Table 7. Bacteriophage ΦX-174* Virus Aerosol Retention Test Results (LifeASSURE™ PFS Series 10" PTFE cartridge filters).

Cartridge Identification	Total Challenge (PFU)	Total Effluent Recovery (PFU)	Virus Filtration Efficiency (VFE)	Log Reduction Value (LRV)
02T003-0095	4.8 x 10^8	none detected	> 99.9999998%	> 8.7
02T003-0102	5.1 x 10^8	none detected	> 99.9999998%	> 8.7
02T003-0111	5.1 x 10^8	none detected	> 99.9999998%	> 8.7
02T009-0035	4.8 x 10^8	none detected	> 99.9999998%	> 8.7
02T009-0040	4.5 x 10^8	none detected	> 99.9999998%	> 8.7
02T009-0041	4.5 x 10^8	none detected	> 99.9999998%	> 8.7
02T020-0008	4.9 x 10^8	none detected	> 99.9999998%	> 8.7
02T020-0091	5.8 x 10^8	none detected	> 99.9999998%	> 8.7
02T020-0093	5.8 x 10^8	none detected	> 99.9999998%	> 8.7

* Master culture concentration: 1.5 x 10^9 PFU/mL

Table 8. Bacteriophage ΦX-174* Virus Aerosol Retention Test Results (LifeASSURE™ PFS series 2.5" PTFE mini-cartridge filters).

Cartridge Identification	Total Challenge (PFU)	Total Effluent Recovery (PFU)	Virus Filtration Efficiency (VFE)	Log Reduction Value (LRV)
02T003-02-0086	5.6×10^8	none detected	> 99.9999998%	> 8.7
02T003-02-0087	5.6×10^8	none detected	> 99.9999998%	> 8.7
02T003-02-0088	5.6×10^8	none detected	> 99.9999998%	> 8.7

* Master culture concentration: 1.5×10^9 PFU/mL

Conclusions:

LifeASSURE™ PFS series 10" PTFE cartridge filters

At a minimum challenge level of 4.5×10^8 PFU, no PFU was detected in the effluent of all nine 10" cartridges.

LifeASSURE™ PFS series 2.5" PTFE mini-cartridge filters

At a challenge level of 5.6×10^8 PFU, no PFU was detected in the effluent of all three 2.5" mini-cartridges.

E. Summary of LifeASSURE™ PFS Series PTFE Filter Integrity Test Parameters

Table 9. Summary of LifeASSURE™ PFS Series PTFE Filter Integrity Test Parameters.

PFS020 Filter Type	Maximum Allowable Forward Flow (cc/min) 25%/75% (v/v) TBA/ H_2O @ 16 psig (1.1 bar) @ 20 °C and 1 atm	Maximum Allowable Forward Flow (cc/min) 60%/40% (v/v) IPA/ H_2O @ 16 psig (1.1 bar) @ 25 °C and 1 atm	Maximum Allowable Forward Flow (cc/min) 70%/30% (v/v) IPA/ H_2O @ 16 psig (1.1 bar) @ 25 °C and 1 atm	Water Intrusion Test Maximum Allowable Flow (ml/min) @ 40 psig (2.8 bar) @ 20 °C and 1 atm	Minimum Bubble Point psig (bar)*
40" cartridge	34.8	142.0	216.0	2.36	16 (1.1)
30" cartridge/ capsule	26.1	106.5	162.0	1.77	16 (1.1)
20" cartridge/ capsule	17.4	71.0	108.0	1.18	16 (1.1)
10" cartridge/ capsule	8.7	35.5	54.0	0.59	16 (1.1)
5" cartridge/ capsule	4.4	17.8	27.0	0.30	16 (1.1)
2.5" capsule	2.2	9.0	13.7	0.15	16 (1.1)
5" mini-cartridge	2.9	11.9	18.2	0.20	16 (1.1)
2.5" mini-cartridge	1.4	5.8	8.8	0.10	16 (1.1)

* Wet with 25%/75% (v/v) TBA/Water, 60%/40% (v/v) IPA/Water, or 70%/30% (v/v) IPA/Water.

F. Air Flow Rate

Method:

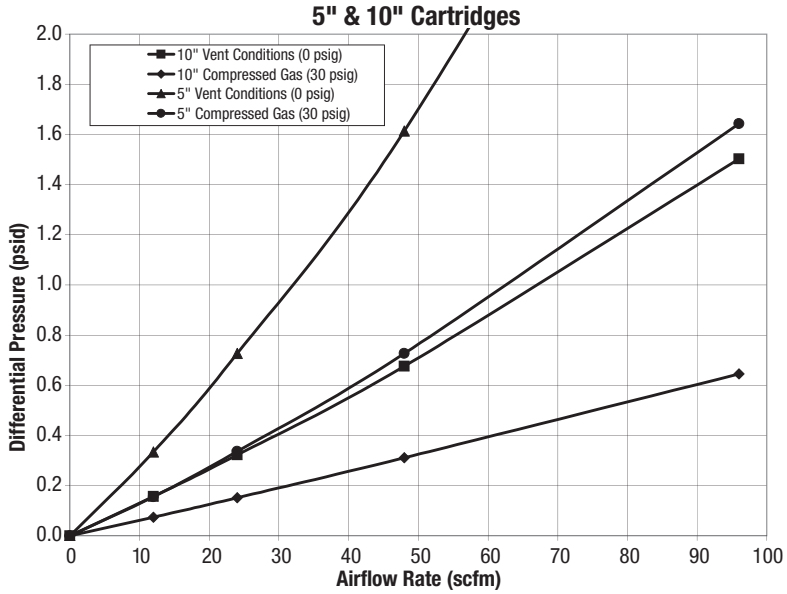
LifeASSURE™ PFS series PTFE filters were taken from multiple production lots for airflow performance testing.

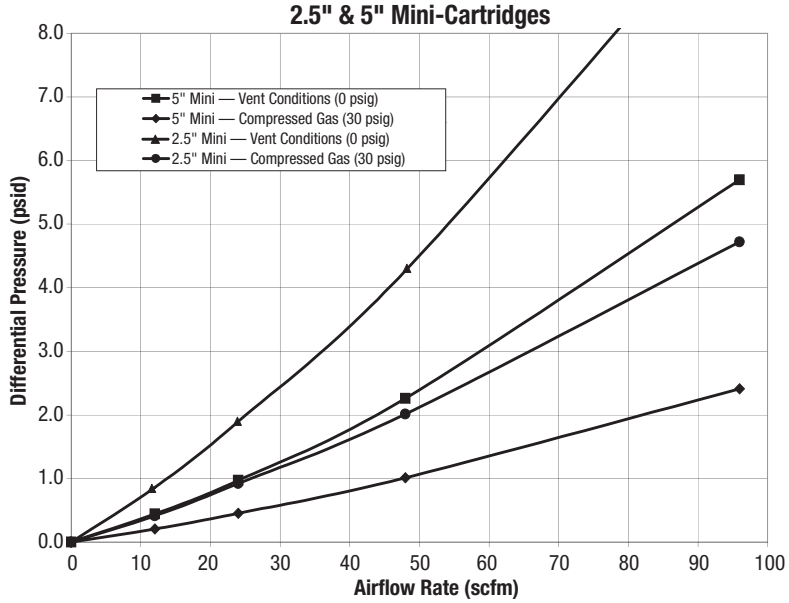
Cartridges were assembled into a filter housing and the differential pressure across the filter assembly was measured while clean filtered air was directed through the housing at a range of controlled flow rates. 5" and 10" cartridges tested utilized the 226 O-ring adapter or mini-cartridge adapter. Differential pressures were measured for both vent (0 psig) and compressed gas (30 psig) conditions. Differential pressures were measured for the empty housing and were subtracted from the measured differential pressures at the appropriate flow rates. Capsule filter assembly results include housing loss.

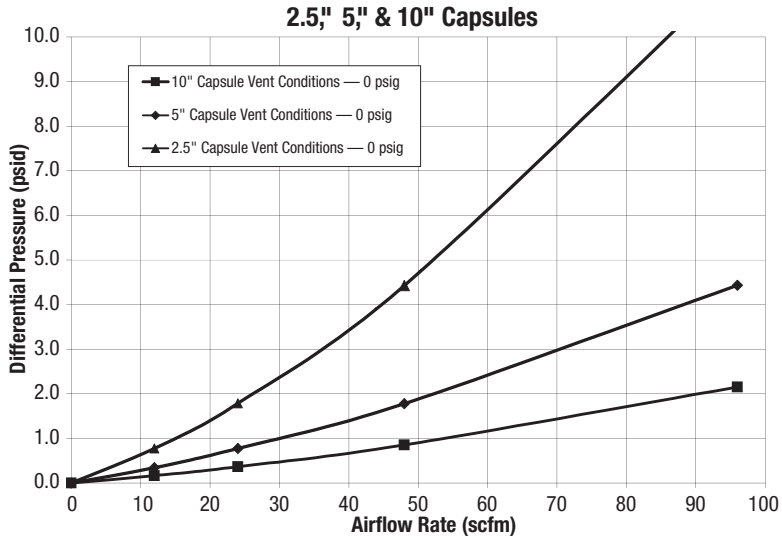
Results:

The airflow graphs on the following page serve to provide typical values for flow data and can be used for sizing filter systems using LifeASSURE PFS series PTFE filters. Housing pressure losses should be added to filter pressure losses when determining system pressure loss. For additional assistance in sizing air filter assemblies, consult 3M Purification Inc. Sales.

Graphs 1–3. Summary of LifeASSURE™ PFS Series PTFE Filters Typical Airflow Rates.







G. Thermal Stress

Cartridge Steam Sterilization

LifeASSURE™ PFS Series PTFE cartridge filters are designed to perform in demanding process conditions. Materials of construction and cartridge design provide an extremely durable envelope that can be *in situ* steam sterilized (or autoclaved) repeatedly without loss of integrity (LifeASSURE PFS series PTFE capsules cannot be *in situ* steam sterilized).

Method:

LifeASSURE PFS series PTFE cartridge filters were taken from multiple production lots for repeat *in situ* steam sterilization performance. Dry cartridges were installed in filter housings and steam sterilized *in situ* at 145 ˚C for a total of 200 sterilization cycles (30 minutes per cycle). Between cycles, the filter housing temperature was allowed to drop below 100 ˚C. Cartridges were steamed in both the forward flow and reverse flow orientation. Cartridges were subjected to both the Water Intrusion Integrity Test at 40 psig test pressure as well as the Forward Flow Integrity Test method in 25%/75% TBA/H_2O tested at 16 psig test pressure.

Results:

The results shown in Table 10 on the following page demonstrate the robustness of the LifeASSURE PFS series PTFE cartridge filters. Cartridges were shown to maintain acceptable integrity values and complete *B. diminuta* retention following 200 steam sterilization cycles. The LifeASSURE PFS series PTFE filters should be considered equally resilient to autoclave sterilization.

Table 10. Integrity Test Results after Repeat Steam Sterilization Cycles at 145 °C for LifeASSURE™ PFS Series 10" PTFE Cartridge Filters.

Serial Number	Steam Flow Direction	Integrity after 200 Steam Cycles		*B. diminuta* Retention (Sterile Effluent)
		WIT (ml/min)	FFIT @ 20 °C (cc/min)	
02T003-0012	Forward	0.35	6.7	Yes
02T003-0022	Forward	0.33	5.7	Yes
02T003-0024	Forward	0.31	5.9	Yes
02T008-0032	Forward	0.38	5.9	Yes
02T008-0033	Forward	0.39	5.6	Yes
02T008-0040	Forward	0.36	5.8	Yes
02T009-0033	Forward	0.47	6.8	Yes
02T009-0042	Forward	0.41	6.5	Yes
02T009-0044	Forward	0.35	5.6	Yes
02T003-0005	Reverse	0.29	4.4	Yes
02T003-0018	Reverse	0.36	7.5	Yes
02T008-0031	Reverse	0.48	6.9	Yes
02T008-0035	Reverse	0.41	5.7	Yes
02T009-0039	Reverse	0.46	6.2	Yes
02T009-0043	Reverse	0.42	6.7	Yes

WIT = Water Intrusion Test with 20 °C water tested at 40 psi.
FFIT = Forward Flow Integrity Test @ 20 °C and 1 atm wet with 25%/75% TBA/H_2O tested at 16 psi.

Capsule autoclave Sterilization

LifeASSURE™ PFS Series PTFE capsule filters are designed to perform in demanding process conditions. Capsule filter materials of construction provide an extremely durable envelope that can be autoclaved repeatedly without loss of integrity (LifeASSURE PFS series PTFE capsule filters cannot be *in situ* steam sterilized).

Method:

LifeASSURE PFS series PTFE capsule filters were taken from multiple production lots for repeat autoclave sterilization performance. Capsule filters were autoclaved with vent connections slightly open, at 126 °C slow exhaust cycle, for up to fifty, 30-minute cycles. Between cycles, capsule filters were allowed to cool to ambient temperature. Capsules were subjected to the Forward Flow Integrity Test method in 25%/75% TBA/H_2O (20 °C) at a test pressure of 16 psi.

Results:

The results shown in Table 11 below demonstrate the robustness of the LifeASSURE PFS PTFE capsule filters tested. Capsules were shown to maintain acceptable integrity values after 50 autoclave sterilization cycles. All capsule filters shown in Table 11 as “Not Done” were examined for burst testing following 30 autoclave cycles. All samples tested exceeded 4 times the capsule pressure rating (75 psig).

Table 11. Integrity Test Results after Repeat Autoclave Cycles at 126 °C for LifeASSURE™ PFS Series 2.5" and 10" PTFE capsule filters.

		Number of 30-minute Cycles		
		0	30	50
Size	Serial Number	FFIT @ 20 °C (cc/min)	FFIT @ 20 °C (cc/min)	FFIT @ 20 °C (cc/min)
2.5" capsule	02T020-0147	0.8	1.3	Not Done
2.5" capsule	02T020-0150	0.5	1.6	1.4
2.5" capsule	02T020-0170	1.0	1.6	1.9
2.5" capsule	02T020-0181	0.9	1.5	Not Done
2.5" capsule	02T020-0188	1.0	2.2	Not Done
2.5" capsule	02T020-0192	1.0	1.9	1.6
10" capsule	03T005-0219	7.2	7.0	Not Done
10" capsule	03T006-0403	6.7	7.0	5.9
10" capsule	03T006-0406	7.0	7.2	5.8
10" capsule	03T006-0408	6.7	6.8	Not Done
10" capsule	03T006-0409	6.0	6.5	6.4
10" capsule	03T006-0413	6.8	6.7	Not Done

FFIT = Forward Flow Integrity Test @ 20 °C and 1 atm wet with 25%/75% TBA/H_2O tested at 16 psi

VI. Effluent Quality

A. Total Non-Volatile Gravimetric Extractables

Method:

LifeASSURE™ PFS Series 10" PTFE cartridge filters were taken from multiple production lots for total non volatile gravimetric extractables (TNVGE) testing. An autoclaved LifeASSURE PFS series PTFE cartridge filter (O-rings removed) was submerged into 1.4 liters of distilled water and held in a 2-liter graduated cylinder while the fluid was gently stirred for four hours. The filter was then removed from the graduated cylinder and the water draining from the filter was allowed to return into the cylinder. The volume of the extract water was concentrated to approximately 20 ml on a hot plate. The concentrated extract was quantitatively transferred into a tared (± 0.1 mg), desiccated, aluminum weighing pan. The contents of the weighing pan were brought to dryness on a hot plate. The weighing pan was dried in a convection oven for 30 minutes at 105 °C and was then desiccated for an additional 30 minutes. Finally, the weighing pan was weighed to determine gross weight (± 0.1 mg). Total, non-volatile gravimetric extractables were equal to the difference between the weighing pan gross and tare weights, in milligrams.

Results:

Total non volatile gravimetric extractable values for LifeASSURE PFS series 10" PTFE cartridge filters taken from multiple production lots are shown in Table 12 below. Results are reported as mg TNVGE corrected for a water control run in parallel. All results were below the quantification limit of 10 mg.

Table 12. Total Non Volatile Gravimetric Extractable Results for LifeASSURE™ PFS Series 10" PTFE Cartridge Filters.

Serial Number	TNVGE (mg/filter)
02T003-0110	< 10*
02T003-0112	< 10
02T003-0092	< 10
02T008-0028	< 10
02T008-0042	< 10
02T008-0039	< 10
02T011-0006	< 10
02T011-0010	< 10
02T011-0024	< 10

* below limit of quantification

B. Effluent Cleanliness

LifeASSURE PFS Series PTFE cartridge filters are designed to contribute minimal particulate to the effluent stream. In this regard, LifeASSURE PFS series 10" cartridge filters were tested from multiple production lots for effluent cleanliness.

Method:

LifeASSURE PFS series 10" PTFE cartridge filters were static soaked in 60%/40% IPA/Water and then pre-flushed with deionized water at 3 gpm for 2 minutes. Four liters of effluent from each cartridge were collected and placed in a laminar flow hood for vacuum filtration. Each effluent sample was vacuum filtered through a 47 mm, 0.8 µm gridded black membrane disc. Each membrane disc was examined microscopically under 100X magnification and particles counted and measured at two size ranges; particles in the first size range were > 10 µm but <2 5 µm, particles in the second size range were > 25 µm. The following table details the particle counts determined microscopically for the LifeASSURE PFS series 10" PTFE cartridge filter.

Results:

The effluent from the LifeASSURE PFS series 10" PTFE cartridge filters tested meet with adequate safety margin the current USP limits under Particulate Matter in Injections (25 particles/ml maximum > 10 µm and 3 particles/ml maximum > 25 µm) with effluent counts determined microscopically. These results document conformance with the requirements for a non-fiber releasing filter per Title 21 of the U.S. CFR parts 211.72 and 210.3 (b) (6).

Table 13. Effluent Particle Count Results for 10" LifeASSURE™ PFS Series PTFE Cartridge Filters.

	Particles/ml	
Serial Number	>10 µm & < 25 µm	> 25 µm
02T003-0099	0.12	0.042
02T008-0024	0.016	0.005
02T009-0032	0.072	0.018
02T011-0010	0.082	0.029
Average	**0.073**	**0.024**

C. Limulus Amebocyte Lysate (LAL) and Oxidizable Substance Testing

LifeASSURE™ PFS Series PTFE filters were designed to provide effluent which meet with adequate safety margin, the specification for endotoxin as stated in USP Volume 24 as well as effluent testing negative for oxidizable substances.

Method:

Limulus amebocyte lysate (LAL) testing (endotoxin testing) was performed according to "USP Bacterial Endotoxin Test" and Associates of Cape Cod technical brief entitled "LAL Pyrotell® for the Detection and Quantification of Gram Negative Bacterial Endotoxins," April, 1990.

An autoclaved, LifeASSURE PFS series PTFE filter was soaked in LAL Reagent Water (LRW) and a sample was collected for the determination of bacterial endotoxins and oxidizable substances. Using de-pyrogenated glassware and endotoxin-free plastic ware, the sample was tested in duplicate for endotoxin using an Associates of Cape Cod (ACC) gel clot method. The method makes use of 0.03 EU/ml sensitivity lysate and Control Standard Endotoxin. 3M Purification Inc.'s procedure is consistent with ACC's recommendations for optimal performance of the method and uses the following controls: 1) endotoxin standard series, 2) positive product control, 3) LRW negative control, and 4) endotoxin spike control.

An aliquot was also taken for oxidizable substances analysis according to USP 24 Oxidizable Substances Test for Purified Water.

Results:

The results in Table 14 show that LifeASSURE PFS series PTFE cartridge filters tested negative for oxidizable substances and < 0.03 EU/mL LAL reactivity, well below the USP limit of < 0.25 EU/ml.

Table 14: LAL and Oxidizable Test Results.

Serial Number	Extractable Endotoxin (EU/ml)	Oxidizable Substances
02T003-0101	< 0.03*	negative
02T003-0090	< 0.03	negative
02T003-0106	< 0.03	negative
02T008-0015	< 0.03	negative
02T008-0025	< 0.03	negative
02T008-0030	< 0.03	negative
02T009-0018	< 0.03	negative
02T009-0021	< 0.03	negative
02T009-0026	< 0.03	negative
02T011-0008	< 0.03	negative
02T011-0016	< 0.03	negative
02T011-0026	< 0.03	negative

* below limit of quantification

VII. Biological Safety Tests

Based upon testing results provided by Toxikon Corporation, all of the materials of construction incorporated into LifeASSURE PFS Series PTFE filters meet the requirements of:

- The USP Biological Reactivity Test: Plastics Class VI — 121 ˚C
- The USP Biological Reactivity Test: Elution Test

Therefore, the filter is both biologically safe and non-cytotoxic according to the above statements. A copy of each test result is attached.

TOXIKON

ISO-9001 Certified

TEST RESULT CERTIFICATE

Sponsor	CUNO Incorporated	**Technical Initiation**	07/24/02
Address	400 Research Parkway Meriden, CT 06450	**Technical Completion**	07/26/02
Contact	Lin Spignesi	**Report Date**	08/09/02
P.O. Number	63468	**Project Number**	02-3988-G2

Test Article	Microfluor II PFS020 10" Cartridge	**Ratio**	6 cm² per 1 mL
Lot #	02T008-0018	**Vehicle**	MEM complete
Study	MEM Elution Test - ISO	**Temp/Time**	37°C for 24 hours

REFERENCE: This study was conducted based on the procedure described in the International Organization for Standardization, Biological Evaluation of Medical Devices-Part 5: Tests for *In Vitro* Cytotoxicity, EN/ISO 10993-5, 1999.

GENERAL PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article extract was determined. Extracts were prepared at 37±1°C for 24 hours in a humidified atmosphere containing 5±1% Carbon dioxide. Positive control (natural rubber) and negative control (negative control plastic) articles were prepared to verify the proper functioning of the test system. The test article or control article extracts were used to replace the maintenance medium of the cell culture. All cultures were incubated in triplicate for 48 hours, at 37±1°C, in a humidified atmosphere containing 5±1% Carbon dioxide. Biological reactivity (cellular degeneration and malformation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity). The test article met the requirements of the test if none of the cultures exposed to the test article showed greater than a Mild Reactivity (Grade 2).

RESULTS: No signs of reactivity (Grade 0) were exhibited by the cell cultures exposed to the test article extract or the negative control article extract at the 48 hour observations. Severe signs of reactivity (Grade 4) were observed for the positive control article extract at the 48 hour observation.

CONCLUSION: The test article is considered non-cytotoxic and meets the requirements of the Elution Test, EN/ISO 10993-5.

AUTHORIZED PERSONNEL:

Leigh Waugh-Cohen, B.A.
Study Director

Miriam Kummailil, B.S.
Quality Assurance

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TOXiKON
Leaders in Life Science and Technology

COMPANION RESULT CERTIFICATION

Sponsor	CUNO, Incorporated	**Technical Initiation**	08/05/02
Address	400 Research Parkway Meriden, CT 06450	**Technical Completion**	08/12/02
Contact	Lin Spignesi	**Report Date**	09/10/02
P.O. Number	63468	**Project Number**	02-3988-G1

Test Article	Microfluor II PFS020 (10" Cartridge)	**Ratio**	120 cm² per 20 mL
Lot #	02T008-0018	**Vehicles**	0.9% USP Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1:20 Alcohol in 0.9% USP NaCl (EtOH), Polyethylene Glycol 400 (PEG)
Study	Biological Test for Plastics Class VI (4 Extracts)	**Temp/Time**	121± 2°C for 1 hour

REFERENCE: USP 25, NF 20, 2002, <88> Biological Reactivity Tests, *In Vivo*.

GENERAL PROCEDURE: The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP 25; including the further dilution of the extracts prepared with PEG. The animals were observed for signs of toxicity and skin reactivity for up to 72 hours post treatment. In addition, the test article components were implanted into the paravertebral musculature of rabbits for 7 days and observed for signs of hemorrhage, inflammation, necrosis, discoloration, and encapsulation, or infection.

RESULTS: None of the mice injected with the test article extracts exhibited any signs of toxicity in the Systemic Injection Test. In addition, none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, edema or clinical toxicity. In both the Systemic and Intracutaneous Tests the controls were normal through 72 hours. Also, the implant sites exhibited no significant signs of hemorrhage, inflammation, necrosis, discoloration, encapsulation, or infection compared with the control sites.

CONCLUSION: The test article meets the requirements of USP 25, NF 20, 2002, for the Biological Test for Plastics, Class VI-121°C.

AUTHORIZED PERSONNEL:

Stacy Pritt DVM
Stacy Pritt, DVM
Study Director

fa Valerie Lambo, B.S. PS
Felice Randi LaMadeleine, B.S.
Quality Assurance

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▸ www.toxikon.com

Please note: The tradename "Microfluor" is now "LifeASSURE." CUNO Incorporated is now 3M Purification Inc.

CERTIFICATE

TÜV

TUV Rheinland of North America, Inc.
12 Commerce Road, Newtown, CT 06470

Hereby certifies that

3M Purification Inc.

32 River Road
Stafford Springs, CT 06076
USA

400 Research Parkway
Meriden, CT 06450
USA

250 South Road
Enfield, CT 06082
USA

Febe 204, Edificio 3,
Parque Industrial Kalos,
Guadalupe, Nuevo León,
C.P. 67190, México

has established and maintains a quality management system for the

Design and Manufacture of Products for Filtration and Ultrafiltration Products and Systems and other Media Platforms for the Potable Water, Fluid Processing, Healthcare, Food and Beverage Markets.

An audit was performed and documented in Report No. 9519.
Proof has been furnished that the requirements according to

ISO 9001:2008

are fulfilled.
Further clarification regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by contacting TRNA.

Certificate Registration No.

74 300 9519

Original Certification Date:
December 1, 1995

Certificate Validity Date:
July 19, 2010

Certificate Modification Date:
July 19, 2010

Certificate Expiration Date:
August 9, 2011

ANAB ACCREDITED

Certification of Management Systems

Appendix B

3M Purification Inc.
Certificate of Quality

ISO 9001:2008 Registered Quality System

Certificate of Quality
for
LifeASSURE™ PFS Series 0.2 µm Pharmaceutical-Grade Filter Products

This Certificate of Quality provides precise information on the quality attributes which support the high standards of consistency and reliability built into 3M Purification Inc. fluid purification products.

(attach label here)

PI0002.1110

LifeASSURE™ PFS Series Product Certification

3M Purification Inc. certifies that this LifeASSURE™ PFS series product (identified by the part, lot, and serial numbers on the attached label) has been manufactured in a controlled environment in a 3M Purification Inc. facility. The 3M Purification Inc. Quality Management System is approved by an accredited registering body to the ISO 9001:2008 Quality Systems Standard.

Drug Master File (DMF)

LifeASSURE PFS series products are included in 3M Purification's Drug Master File on record with the U.S. FDA. Specific DMF numbers are available on request.

Identification and Traceability

LifeASSURE PFS series products are marked with a unique serial number providing full traceability through records of manufacturing and raw material components.

Quality Assurance Qualification Criteria

This product design has successfully passed a series of rigorous qualification tests demonstrating its ability to meet the following performance criteria:

Component Material Toxicity

Component materials were tested and meet the criteria listed in the current revision of the USP Class VI Biological Safety Test for Plastics. These products are also made from materials listed for food contact per Title 21 of the U.S. Code of Federal Regulations (CFR), parts 170-199.

Virus Aerosol Retention

This product has been qualified to retain an aerosol challenge of ΦX-174 virus exceeding 10^7 PFU per 10" cartridge.

Thermal Stress

Sample filters maintained integrity following multiple cycles of *in situ* steam or autoclave exposure.

Non-Fiber Releasing

Meets the current USP limits under Particulate Matter in Injections with effluent counts determined microscopically. This product conforms to requirements for a non-fiber releasing filter per Title 21 of U.S. Code of Federal Regulations (CFR) parts 211.72 and 210.3 (b) (6).

Airflow Rate and Pressure Drop

Sample filters and capsules were tested and passed minimum airflow rate and pressure drop specifications.

Gravimetric Extractables

Sample LifeASSURE PFS series products were tested and passed maximum extractables specification after extraction in distilled water at ambient temperature.

3M Purification Inc.
Certificate of Quality

Quality Assurance Lot Release Criteria

This manufacturing lot was sampled, tested, and released by Quality Assurance based on the following tests:

Bacterial Retention
Sample LifeASSURE PFS series membrane was shown to be 100% retentive of a minimum *Brevundimonas diminuta* (ATCC 19146) challenge of 10^7CFU/cm^2 using ASTM method F838-05.

100% Integrity Tested
This LifeASSURE PFS series product successfully passed a forward flow integrity test. The integrity test specification has been correlated with bacteria retention.

USP Bacterial Endotoxin
Sample LifeASSURE PFS series product met current USP requirements after flushing, as determined by the Limulus Amebocyte Lysate (LAL) Gel Clot Test.

USP Oxidizable Substances
Sample LifeASSURE PFS series product was tested and shown to be negative for oxidizable substances using a potassium permanganate test method.

LifeASSURE™ PFS series products are not supplied sterile.

Only original *Certificates of Quality* are authorized by 3M Purification Inc.

Further information is available by referencing the LifeASSURE PFS series Filter Validation Guide (70-0201-8842-4) or by contacting 3M Purification Inc., at 800-243-6894.

L. Della Terra

Quality Assurance Manager

3M Purification Inc.
400 Research Parkway
Meriden, CT 06450, U.S.A.
Tel (800) 243-6894
(203) 237-5541
Fax (203) 238-8977
www.3Mpurification.com

Appendix C

Material Safety Data Sheet

This material safety data sheet (MSDS) is provided as a courtesy in response to a customer request. This product is not regulated under, and a MSDS is not required for this product by the OSHA Hazard Communication Standard (29 CFR 1910.1200) because, when used as recommended or under ordinary conditions, it should not present a health and safety hazard. However, use or processing of the product not in accordance with the product's recommendations or not under ordinary conditions may affect the performance of the product and may present potential health and safety hazards.

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME:	LifeASSURE™ PFS Series Filter Cartridges
DATE:	December 2009
COMPANY:	3M Purification Inc., 400 Research Parkway, Meriden, CT 06450

Product specific use:

FOR CHEMICAL EMERGENCY, SPILL, LEAK, FIRE, EXPOSURE OR ACCIDENT
EMERGENCY PHONE: 1-800-364-3577 or (651) 737-6501 (24 hours)
for non-emergency information, call (203) 238-8965

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS No.	% by Wt.

3. HAZARDS IDENTIFICATION

Odor, Color, Grade: Refer to Section 9.
General Physical Form: Solid

Immediate health, physical, and environmental hazards: This product, when used under reasonable conditions and in accordance with the directions for use, should not present a health hazard. However, use or processing of the product in a manner not in accordance with the product's directions for use may affect the performance of the product and may present potential health and safety hazards.

POTENTIAL HEALTH EFFECTS

EYE CONTACT: No health effects are expected.

SKIN CONTACT: No health effects are expected.

INHALATION: No health effects are expected.

INGESTION: No health effects are expected.

4. FIRST AID MEASURES

EYES CONTACT: No need for first aid is anticipated.

SKIN CONTACT: No need for first aid is anticipated.

INHALATION: No need for first aid is anticipated.

IF SWALLOWED: No need for first aid is anticipated.

5. FIRE FIGHTING MEASURES

FLASH POINT: N/A

EXTINGUISHING MEDIA: Use fire extinguishers with class B extinguishing agents (e.g., dry chemical, carbon dioxide).

UNUSUAL FIRE AND EXPLOSION HAZARDS: No unusual fire or explosion hazards are anticipated.

FIRE FIGHTING EQUIPMENT: Wear full protective equipment (Bunker Gear) and a self-contained breathing apparatus (SCBA).

6. ACCIDENTAL RELEASE MEASURES

ACCIDENTAL RELEASE MEASURES: Not applicable.

7. HANDLING AND STORAGE

HANDLING: Keep out of the reach of children. This product is considered to be an article which does not release or otherwise result in exposure to a hazardous chemical under normal use conditions. Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below Occupational Exposure Limits. If ventilation is not adequate, use respiratory protection equipment.
STORAGE: Not applicable.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

EYE PROTECTION: Not applicable.

SKIN PROTECTION: Not applicable.

RESPIRATORY PROTECTION: Under normal use conditions, airborne exposures are not expected to be significant enough to require respiratory protection.

PREVENTION OF SWALLOWING: Not applicable.

9. PHYSICAL AND CHEMICAL PROPERTIES

Odor, Color, Grade:	Appearance and Odor: Filter cartridges are cylindrical, white and solid. Filter housings are also white and constructed with high impact plastic. These products are odorless.
General Physical Form:	Solid
Autoignition temperature	*Not Applicable*
Flash Point	*Not Applicable*
Flammable Limits - LEL	*Not Applicable*
Flammable Limits - UEL	*Not Applicable*
Boiling point	*Not Applicable*
Density	*Not Applicable*
Vapor Density	*Not Applicable*
Vapor Pressure	*Not Applicable*
Specific Gravity	*Not Applicable*
pH	*Not Applicable*
Melting point	*Not Applicable*
Solubility in Water	Nil
Evaporation rate	*Not Applicable*
Percent volatile	*Not Applicable*
Viscosity	*Not Applicable*

10. STABILITY AND REACTIVITY

STABILITY:

MATERIALS TO AVOID:

HAZARDOUS DECOMPOSITION PRODUCTS:

HAZARDOUS POLYMERIZATION: Will not occur.

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS

Substance	**Condition**

HAZARDOUS DECOMPOSITION: Under recommended usage conditions, hazardous decomposition products are not expected. Hazardous decomposition products may occur as a result of oxidation, heating, or reaction with another material.

11. TOXICOLOGICAL INFORMATION

Please contact the address listed on the first page of the MSDS for Toxicological Information on this material and/or its components.

ECOTOXICOLOGICAL INFORMATION: Not applicable.

CHEMICAL FATE INFORMATION: Not applicable.

12. ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION: Not determined.

CHEMICAL FATE INFORMATION: Not determined.

13. DISPOSAL CONSIDERATIONS

Dispose of waste product in a sanitary landfill. As a disposal alternative, incinerate in an industrial or commercial facility in the presence of a combustible material. WARNING: To reduce the risks associated with improper disposal and/or handling of contaminates in used filters: Take appropriate steps to access the disposal required for any altered product or materials added to the product. (Alteration of the product or addition of other materials to the product may require different disposal methods.)

14. TRANSPORTATION INFORMATION

Please contact the emergency numbers listed on the first page of the MSDS for Transportation Information for this material.

15. REGULATORY INFORMATION

Chemical Inventories:
This product is an article as defined by TSCA regulations, and is exempt from TSCA Inventory listing requirements. Contact 3M Purification for more information.

311/312 Hazard Categories:
Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No Immediate Hazard - No
Delayed Hazard - No

US FEDERAL REGULATIONS
Contact 3M Purification for more information.

STATE REGULATIONS
Contact 3M Purification for more information.

INTERNATIONAL REGULATIONS
Contact 3M Purification for more information.

16. OTHER INFORMATION

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3M Purification Inc. MSDSs are available at www.3M.com

Appendix D

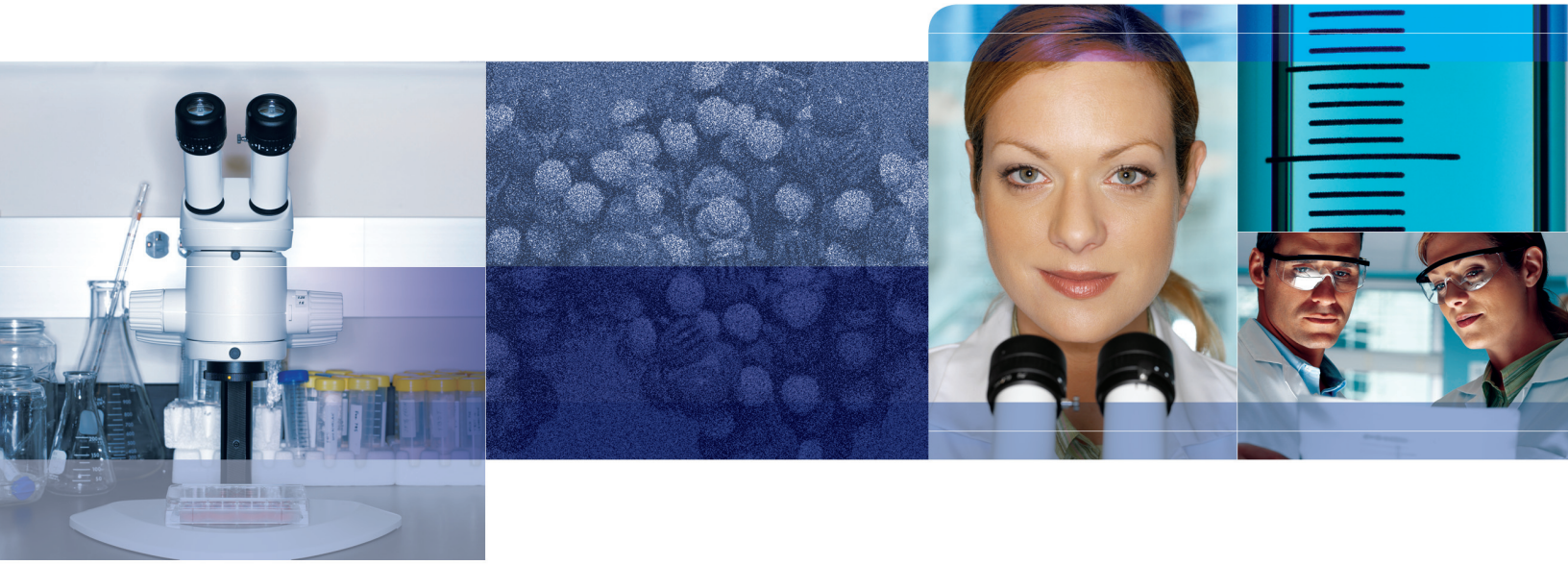
Animal Derived Component Statement

3M Purification Inc. ("3M PI") understands the continued public interest and the increased regulatory scrutiny concerning the transmission of Bovine Spongiform Encephalopathy (BSE) and other Transmissible Spongiform Encephalopathies (TSE). In order to address these issues, the following statement is offered:

In order to assess the BSE/TSE risk associated with the LifeASSURE™ PFS Series PTFE filter product, we have contacted our suppliers of raw materials and performed an evaluation of our production processes to determine if any of the materials used are of animal origin. The result of our survey and inquiries of our raw material suppliers has revealed that the polypropylene resins used to mold parts and the thermoplastic rubber used in the edge seals may contain tallow derivatives and certain rubber gaskets could contain a stearic acid that is used as an activator in the vulcanization process. We can state, however, that these parts which use tallow derivatives and stearic acid are processed at conditions conforming to the requirements of the European Agency for the Evaluation of Medicinal Products EMEA/410/01 rev. 2 and are thought unlikely to be infectious, per said regulation.

Based on this, the likelihood of BSE or other TSE prions being present in the LifeASSURE PFS series PTFE filter products is very low. Therefore, the exposure risk to your product using these filters is also minimally very low. Should you have any questions, please do not hesitate to contact us.

3M Purification Inc. Corporate Worldwide Quality Assurance



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The information described in this literature is accurate to the best of our knowledge. A variety of factors, however, can affect the performance of the Product(s) in a particular application, some of which are uniquely within your knowledge and control. **INFORMATION IS SUPPLIED UPON THE CONDITION THAT THE PERSONS RECEIVING THE SAME WILL MAKE THEIR OWN DETERMINATION AS TO ITS SUITABILITY FOR THEIR USE. IN NO EVENT WILL 3M PURIFICATION INC. BE RESPONSIBLE FOR DAMAGES OF ANY NATURE WHATSOEVER RESULTING FROM THE USE OF OR RELIANCE UPON INFORMATION.**

It is your responsibility to determine if additional testing or information is required and if this product is fit for a particular purpose and suitable in your specific application.

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70-0201-8843-2 REV 1110