Sterile Air/Vent Filter Cartridges

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Emflon PFR filters have been developed for use as air and gas-sterilizing filters in the pharmaceutical and biotechnology industries. The Pall PTFE membrane is inherently hydrophobic, chemically inert, and designed specifically for removal of contaminating bacteria and viruses.[1] Emflon PFR filters meet the ever-increasing demand for air filters with greater strength, longer life, and the ability to withstand the rigors of *in situ* steaming in the forward or reverse direction.

Emflon PFR filters were tested by liquid challenge tests using *Brevundimonas diminuta* (ATCC 19146), in accordance with the FDA guidelines on Sterile Products produced by Aseptic Processing (2004).[2] These tests demonstrated that Emflon PFR filters retain 10^7 *Brevundimonas diminuta* per cm^2 in liquid (Table 1). The forward flow integrity test was shown to be a suitable non-destructive integrity test for Emflon PFR filters, and test parameters correlated to liquid bacterial challenge tests have been set.

STUDIES ON REMOVAL EFFICIENCY

Various aerosol microbial challenge tests were also performed on typical production filters. These tests demonstrated that Emflon PFR filters retain high levels of aerosol bacteria, bacteriophage, and spores. A summary of the aerosol challenge data is shown in Table 2.

RESISTANCE TO STEAM STERILIZATION

Emflon PFR filter cartridges have been demonstrated to retain integrity after repeated steam in place cycles, under the conditions listed in Table 3.

The data presented demonstrate that Emflon PFR filters withstand exposure to air at elevated temperatures. Based on cyclic exposure to steam and hot air, the results indicate that Emflon PFR filters will retain integrity following exposure of well over one year at 60 °C (140 °F).

Table 1. Correlation of forward flow with *Brevundimonas diminuta* retention for Emflon PFR filters (Part Number AB1PFR7PVH4)

Filter number	Forward flow* (mL/min)	Sterile effluent	Titer reduction
1	3.3	Yes	> 1.69×10^{11}
2	3.4	Yes	> 1.10×10^{11}
3	3.5	Yes	> 1.69×10^{11}
4	3.6	Yes	> 1.10×10^{11}
5	3.7	Yes	> 1.93×10^{11}
6	3.8	Yes	> 1.33×10^{11}
7	3.9	Yes	> 1.33×10^{11}
8	4.0	Yes	> 1.93×10^{11}
9	4.1	Yes	> 1.44×10^{11}
10	4.5	Yes	> 1.93×10^{11}
11	4.7	Yes	> 1.44×10^{11}
12	5.7	Yes	> 1.44×10^{11}
13	7.0	No	1×10^5
14	7.5	No	1×10^5
15	10.0	Yes	> 1.51×10^{11}
16	36.0	No	1.51×10^6

*Forward flow values at 1,100 mbar (16 psi) air test pressure, wet with 25% (v/v) tertiary butyl alcohol in water. Maximum allowable limit 5.5 mL/min. It was found that all of the filters with forward flow values ≤ 5.7 mL/min gave sterile effluent when challenged with > 1×10^{11} CFU of *B. diminuta* per filter. Of the four filters with forward flow values between 7.0 and 36.0 mL/min, one gave sterile effluent and the remaining three gave titer reductions between 1×10^5 and 1.51×10^6.

CONCLUSIONS

Pall Emflon PFR sterilizing-grade filter cartridges are designed to completely remove bacteria, viruses, and particles from air and gas streams, even in the presence of humidity and moisture. Emflon PFR filters are built to withstand adverse *in situ* steaming conditions in either the forward or reverse direction. Emflon PFR filters provide high assurance of filter integrity and long-life, even during continuous use in hot air up to 60 °C (140 °F) and after repeat steamings for a typical period of up to 12 months. This is combined with high flow-rates and excellent de-wetting characteristics resulting in very economical filtration through the use of smaller installations and reduced energy costs. In addition, the filters can be tested *in situ* by the forward flow integrity test correlated to liquid bacterial challenge. The Emflon PFR filter cartridges are ideal for pharmaceutical and applications such as fermenter and bioreactor inlet air and exhaust venting, sterile process air, and sterile venting of tanks, lyophilizers, and autoclaves.

REFERENCES

1. Pall Validation Guide for Pall Emflon PFR Filter Cartridges USTR2114.
2. US Food and Drug Administration. Guidance for industry. Sterile Products produced by aseptic processing. Rockville, MD; 2004 Sep.

Table 2. Studies on removal efficiency

Aerosol challenge suspension	Direction of flow during challenge	Titer reduction result*
Brevundimonas diminuta (ATCC 19146)	Forward (out to in)	> 2.29×10^5
Brevundimonas diminuta (ATCC 19146)	Reverse (in to out)	> 3.10×10^8
Brevundimonas diminuta (ATCC 19146)	Forward 30 day test	> 6.8×10^{10}
Bacteriophage PP7	Forward	> 2.4×10^{11}
Bacteriophage MS-2	Forward	> 2.3×10^{10}
Bacillus subtilis Var niger spores	Forward	> 2.3×10^{10}
Bacillus subtilis Var niger spores	Forward 30 day test	> 2.6×10^{10}

*Minimum titer reduction observed during testing

Table 3. Resistance to steam sterilization

Test	Temperature	Steam flow direction	Cycle time	Differential pressure	Total steam exposure
A	142 °C (288 °F)	Forward	11 h	< 300 mbar (4.3 psid)	176 h
B	142 °C (288 °F)	Forward	1 h	< 300 mbar (4.3 psid)	165 h
C	125 °C (257 °F)	Forward	1 h	1,000 mbar (14.5 psid)	30 h
D	125 °C (257 °F)	Reverse	1 h	500 mbar (7.2 psid)	40 h