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PAO Compatible ePTFE Technology HEPA Filters for Cleanroom Pharmaceutical Applications

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Abstract

Biotechnological and pharmaceutical processes use HEPA (High Efficiency Particulate Air) and ULPA (Ultra-Low Particulate Air) air filters. Until recently, these filters were predominantly made out of microglass filter media, making them very fragile and prone to damage and potential leakage.

Technological advancements in filtration media have now translated into high durability (reduced contamination risks) and low pressure drop (lower energy use) media. This high durability HEPA and ULPA filter media is a composite of ePTFE (expanded polytetrafluoroethylene) membranes and various polymer support layers. ePTFE membrane media is engineered to increase reliability, compared to conventional microglass HEPA media.

Historically, ePTFE filters have been the premium filter for microelectronic applications, where they are not exposed to hydrocarbon aerosol testing. Filters typically overload and foul when exposed to high concentrations of hydrocarbons, and ePTFE filters typically load more quickly than other types of filters. This is due to the high surface energy of the ePTFE membrane, which makes it very oleophillic in nature.

However, pharmaceutical grade HEPA filters are required to go through a semi-annual test for leaks that utilizes PAO (polyalphaoleofin) aerosol (typical concentration around 15 micrograms/liters). PAO aerosol particles can foul the ePTFE membrane, which leads to saturation of the pores in the membrane and results in a spike in pressure drop. A study performed by Ron Roberts of Bayer Pharmaceuticals, published in 2003 in the Journal of IEST, stated that ePTFE filters were not suitable for pharmaceutical applications, since they could not withstand the PAO challenge test. The ePTFE filter used in the Roberts study was a microelectronics grade filter.

Over the last decade, the use of ePTFE filters in life science applications has been rather gradual, due to the filters' sensitivity to PAO loading. This paper is focused on studying a new pharmaceutical grade ePTFE technology that has higher PAO loading capacities, therefore allowing this HEPA media to withstand high concentrations of PAO aerosol, just as microglass does. This ePTFE media will therefore have a service life equal to or greater than microglass HEPA filters.

Keywords

ePTFE Membrane, Gel Seal leaks, Pharmaceutical HEPA filters, PAO leak test

1. Background

HEPA filtration requires filter designs to meet demanding efficiency requirements for critical applications, in which airborne contaminants have to be carefully monitored. Biotechnology, Pharmaceutical, Semiconductor, and Nuclear industries are examples of these critical applications.

Another important design aspect of a HEPA filter, in addition to high efficiency, is energy consumption, which is determined by the resistance to flow in the filter. In order to capture sub-micron particulates from the air, HEPA filters must have very fine pore size distribution in the filter media, which can cause the friction coefficient to be significantly higher. Traditional HEPA filter media has been made from borosilicate glass fibers. The fine fibers in this type of filter media impart high particulate capture efficiencies for ASHRAE, HEPA and ULPA filtration. Wet-laid media production has been in place since the 1950s, and the processes are well established, due to years of experience in operation and optimization of media properties, necessary volumes, and cost.

However, microglass HEPA media usually demonstrates low durability. These filters are susceptible to failure that can be caused by various reasons, such as handling, testing and validation, cleaning, and unintended contact. Figure 1 shows a flow chart of various failure modes in microglass HEPA filters. Pharmaceutical grade cleanrooms require semiannual testing with PAO to check for any leaks, and due to the poor mechanical strength of microglass media, it can be easily damaged during testing/validation or other sources mentioned in Figure 1.

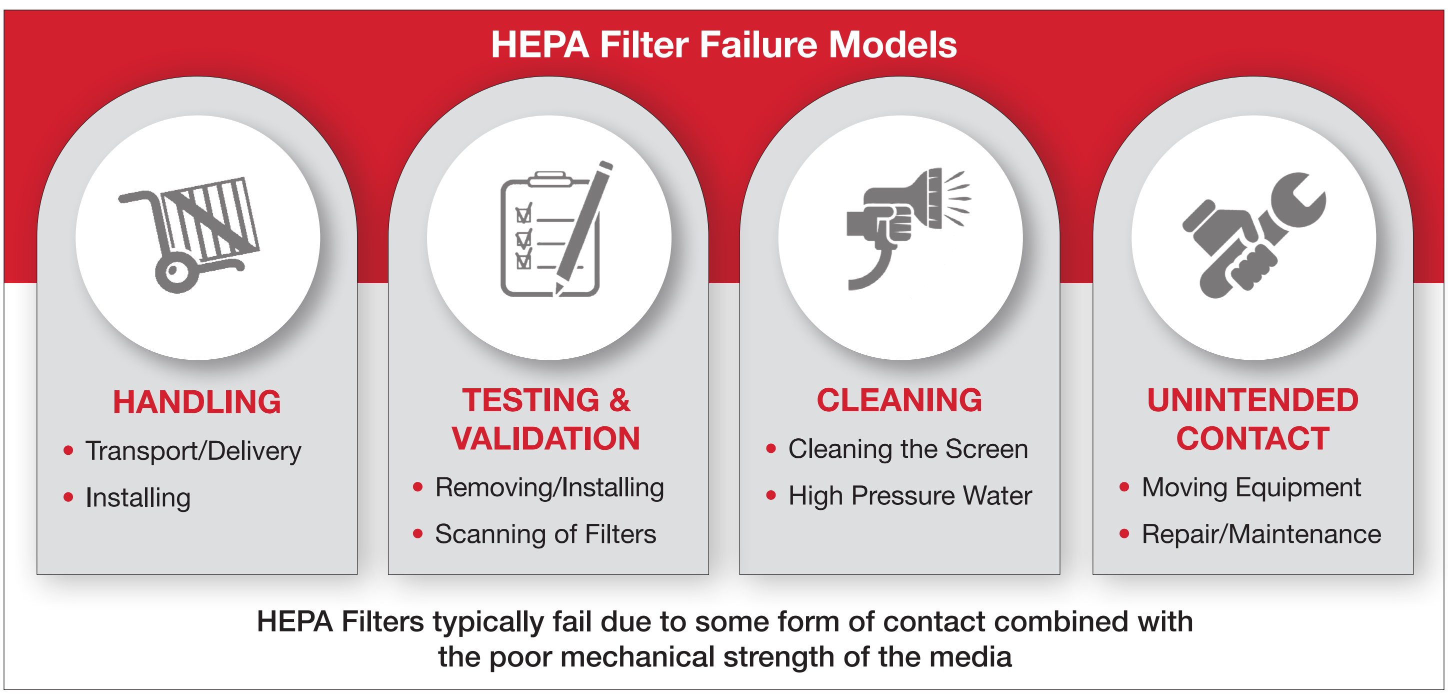

Figure 1: *Failure modes in HEPA filters*

Table 1: Comparison of physical properties of Microglass and ePTFE

	Microglass HEPA	Conventional ePTFE	PAO Tolerant ePTFE
PAO loading compatibility	Average	Poor	Excellent
PAO holding capacity g PAO/m^2 of media	16-18	2-3	38-40
PAO Test aerosol concentrations, μg/l	˜0.03-0.10 or 10-12	˜0.03-0.10	˜0.03-0.10 or 10-20
Abrasion resistant, cycles, per DIN EN 12947-2 Rub cycle on flat media, formation of 0.5 mm hole, 9 kPa force	20	20,000	No Data
Tensile strength, flat sheet, Newton, per DIN EN 29073-3 Test speed of 100 mm/min until breaking of media sample 5 cm wide	41.6	312	No Data
Tensile strength, folded sheet, Newton, per DIN EN 29073-3 Folded at 4.8-5.0 cm interval, test speed of 1oo mm/min until breaking, 5 cm wide	3.8	318	No Data
Burst pressure, flat sheet, kg/cm^2 Flat media sheet on a test surface of 10 cm^2	0.1406	6.4	>6.4
Pressure drop, pascals Airflow of 0.0053 m/sec through media	89	38	43
Energy consumption ratio Compared to microglass	1.00	0.43	0.48
Hydrophobic properties	Excellent	Excellent	Excellent
Chemical resistance to decontamination, sterilization agents	Good	Excellent	Excellent

This risk can be mitigated by the use of durable ePTFE-based HEPA filters. Table 1 shows a comparison of the physical properties of ePTFE and microglass HEPA filters, highlighting PAO holding capacity and mechanical strength. This table demonstrates that durable ePTFE media has a high PAO holding capacity and is suitable for pharmaceutical applications.

Membrane technology has made significant growth in the past few decades, covering a wide variety of applications. Filtration is one of the key unit operations that ePTFE membranes are used in. ePTFE media has unique chemical and physical properties that gives it desirable characteristics for air filtration applications, offering a lower pressure drop than conventional HEPA microglass.

2. Comparison Between Microglass and ePTFE HEPA Filters

Conventional ePTFE membrane filters cannot tolerate high concentrations of PAO aerosol (~15 μg/l), due to their hydrophobic properties. These filters quickly become saturated, and the resistance to airflow increases rapidly. This sensitivity to PAO and other hydrocarbons has therefore posed an obstacle for the implementation of ePTFE filters in pharmaceutical applications. However, the electronics and semiconductor industry does not use PAO aerosol for testing, and ePTFE filters are widely used in that industry.

Ron Robert's study in 2003 concluded, "ePTFE is not suited for the intended [pharmaceutical] application requiring semiannual certification using a PAO-based aerosol challenge." The study reported an increase of 96% in pressure drop in an ePTFE filter, due to exposure to a PAO aerosol concentration of 15 μg/l for 5 hours. The ePTFE filter used in this study was microelectronics grade.

AAF International has developed a PAO-tolerant ePTFE membrane that can withstand high concentrations of PAO, just as microglass HEPA filters can. This enhanced media design offers an increased tolerance to hydrocarbon-based aerosols.

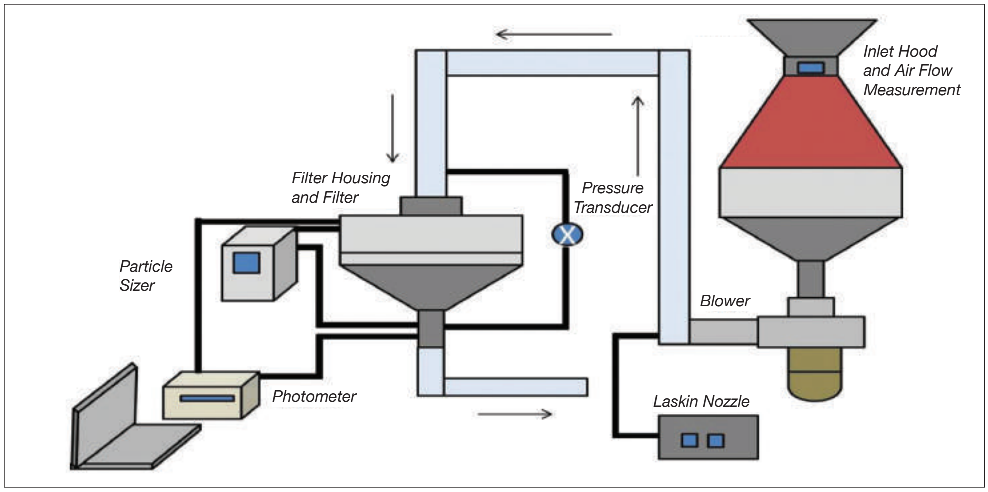

Figure 2: *Test schematic for PAO loading studies*

3. PAO Loading Studies on ePTFE and Glass HEPA Filters

Conventional ePTFE membrane filters typically cannot handle high concentrations (10-20 μg/l) of PAO for extended periods of time. The high levels of PAO saturate the ePTFE media, reduce airflow, and increase the pressure drop across the filter. AAF's ePTFE media is a next generation of ePTFE filter media that exhibits high tolerances to PAO loading.

PAO loading tests were carried out similar to those reported in the article by Roberts et al. to compare the impacts of PAO exposure on conventional ePTFE, microglass (AstroCel® II), and PAO-tolerant ePTFE filter media. Filter loading data was generated for the three media types by monitoring the differential pressure drop across the 592mm x 592mm x 69mm filters as they loaded with PAO. The test setup schematic is shown in figure 3. The airflow was maintained at approximately 300 cfm during the study, using a low flow balometer, followed by a HEPA filter. The PAO aerosol was injected at ~45 μg/l using a laskin nozzle, and then the aerosol-laden air was sent to the challenged filters. Particle concentration and pressure drop were measured across the filters at regular intervals. The results are shown in Figure 3. Test results showed an increased PAO holding capacity for the next generation ePTFE membrane, exceeding the tolerance of the microglass filter media.

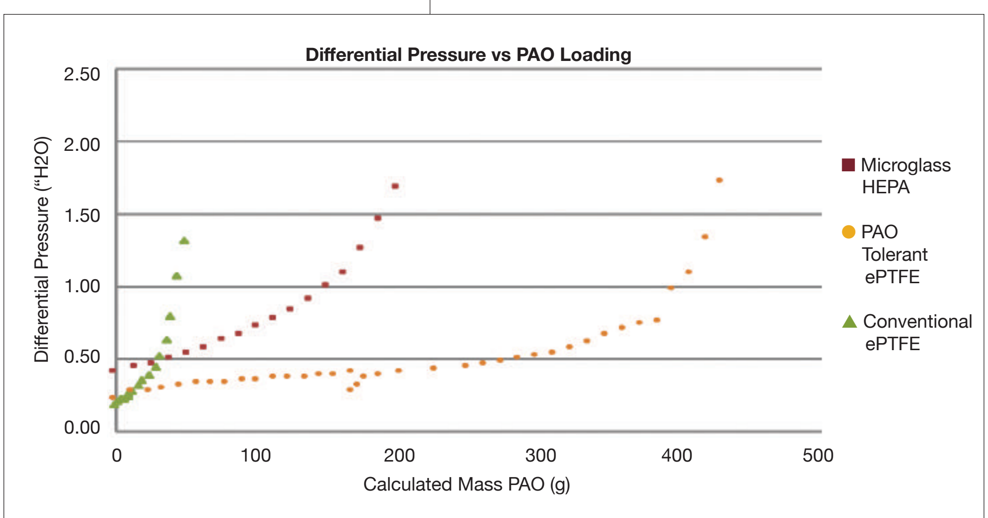

Figure 3: *PAO loading capacity for conventional oil sensitive ePTFE, micro glass, and PAO tolerant next generation ePTFE.*

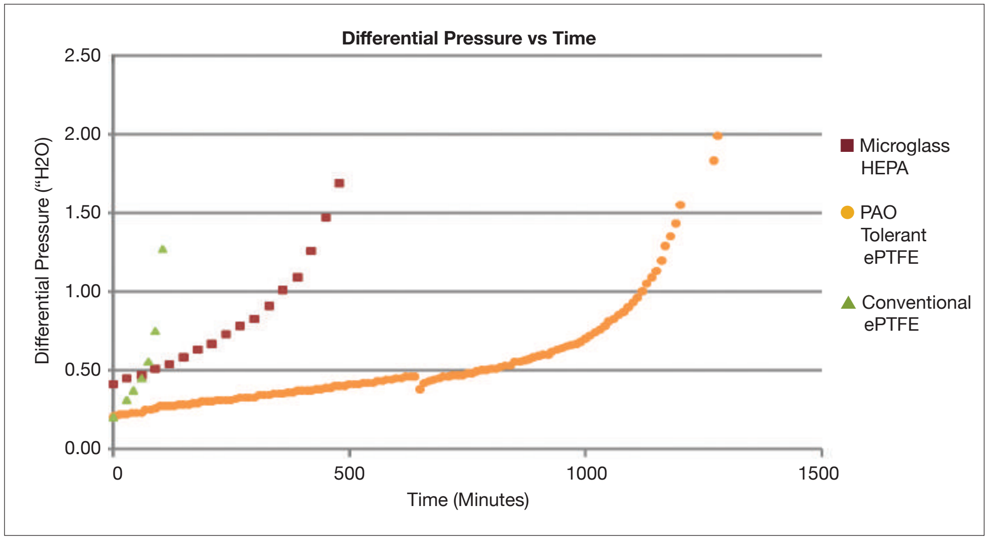

Figure 4: *Differential pressure drop increase over time*

This type of ePTFE filter overcomes the issues associated with high levels of PAO exposure due to semiannual certification of in-situ HEPA filters. Figure 4 shows the relative time for PAO loading and the pressure drop increase in the test. Due to their high tolerance to oil, the PAO-tolerant ePTFE filters can serve as a "drop in" replacement for traditional microglass media filters. Traditional photometer test methods can now be employed to validate the integrity of the ePTFE filters without compromising the filter's performance.

Particle counts were taken at the outlet of the filter test station (post mixing) to determine relative changes in filter efficiencies as the filters loaded with PAO. A 454:1 dilutor was used in combination with the particle counter when taking 30-second downstream counts.

Due to the high concentration of PAO challenge (~45μg/l), the upstream challenge had to be approximated with a conversion factor of 300 million particles/ft3 for 1μg/l of PAO challenge as measured by the photometer. This conversion was based on historical data gathered from the ISPE article "Alternative Methods for HEPA Filter Leak Detection" (Meek, Milholland, Litauski), and the ISPE article "Alternative Test Methodology for In-Situ Testing of ePTFE HEPA Filters for Pharmaceutical Applications" (Bryan, Kitch, Meek, Nance), as well as additional work/studies performed during this testing.

4. Conclusion

Conventional ePTFE membrane filters typically cannot handle high concentrations (10-20 μg/l) of PAO for extended periods of time. AAF's PAO-tolerant ePTFE media is a next generation of ePTFE filter media that exhibits high PAO loading, just as traditional microglass media filters do. The next generation ePTFE based filters overcome the issues associated with high levels of PAO exposure, indicating that these filters can be tested with traditional photometer test methods found in the pharmaceutical industry, based on NEBB procedural standards for certified cleanroom testing.

If PAO loading is the only factor considered for ePTFE filter types, the data suggests an expected life of over 5 years for test conditions involving PAO challenge concentrations of 30μg/l (over two times the expected testing rate) and exposure times of 5 hours per filter for each semi-annual test. It should be noted that contaminants such as dust and other particulates could significantly impact the results, along with using the correct PAO tolerant ePTFE.

This now allows the pharmaceutical industry to take advantage of the superior performance and energy consumption of ePTFE filters in their applications.

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Acknowledgements:

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