



Life Sciences

Application Note

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Sterile Vent Filtration on Ozonated Water Tanks

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Introduction

Many pharmaceutical processes require large volumes of water. It is critical that the pharmaceutical grade water used is protected from particulate or microorganism contamination to ensure that process operations do not inadvertently become contaminated. Several approaches can be used to ensure that the water remains free from contamination, including storage of Purified Water, Highly Purified Water or Water for Injection (WFI) at a minimum temperature of 80 °C (176 °F) in order to discourage microbial growth in the storage system. Another approach is to add ozone (which acts as an antimicrobial and oxidizing agent) to ambient water (and in exceptional cases to hot water) storage and distribution systems. The primary focus for ozone disinfection of water has been USP Purified Water in the US and Highly Purified Water in other areas of the world. However the concept of Water for Injection (WFI) sanitization with ozone was considered as well.

Usually, the water is stored in tanks fitted with a sterilizing-grade vent filter to ensure that the tank can be properly vented for filling and emptying, without the risk of secondary contamination from the tank environment. This document discusses considerations for selecting a vent filter for a hot or ambient water tank that is subjected to ozonation.

Ozone is sparingly soluble in water and due to a tendency to off-gas, ozone can accumulate in the tank head space and the filter housing installed at the recirculating water system. Gas movement into or out of the filter housing is caused by tank filling and emptying typically influencing the amount of ozone which is in contact with the plastic material of the filter in these applications. Ozone evaporation from the ozonated water into the gas phase or an elevated temperature of the gas phase could cause oxidation effects to the polypropylene hardware used in many vent filters installed in the filter housing. Oxidation can result in brittleness and loss of plasticity of sterilizing-grade vent filters. In addition to the polypropylene hardware, the most vulnerable parts of many vent filters are the support and drainage layers made from polypropylene fibers. The other components in the filter such as polytetrafluoroethylene (PTFE) membrane, silicone O-rings and 316 L stainless steel used in the filter housings have excellent resistance to ozone.

Sterile Venting of Hot and Ozonated Water Tanks

For sterile gas filters, polypropylene is the most common material used for filter element hardware construction. However, as polypropylene has only limited resistance to ozone, these filters have a limited life in ozone service. The polypropylene drainage layers became brittle and powdery due to oxidative attacks from the ozone or the hot air above the water. The limited resistance of polypropylene when exposed to ozone is also documented in literature, such as corrosion resistance tables¹. For this reason, the use of standard vent filter cartridges such as Emflon® PFR or Emflon II filters under oxidative conditions requires frequent changeout of filter cartridges in order to avoid degradation of the filter materials.

The alteration of the hardware of the filter elements can lead to severe effects during use, including:

- Material and particle input into WFI or pure water storage tanks
- Passage of microorganisms through damaged filter cartridge components
- Failure of filter cartridge integrity and integrity test procedures

Pall developed Emflon HTPFR filters to provide a longer vent filter service life in applications that involve a highly-oxidative environment. Emflon HTPFR filters contain polytetrafluoroethylene membrane and have been developed with a special support and drainage material made from polyphenylene sulfide (PPS) which is more robust in oxidative environments. In addition, the polypropylene hardware used for Emflon HTPFR filters has been optimized to have greater resistance to oxidation. To confirm the suitability, compatibility and resistance of Emflon HTPFR filter cartridges on ozonated water tanks, several on-site investigations were conducted with Emflon HTPFR filters as the sterile vent filter on different pharmaceutical water system tanks, and with ozone as a disinfectant.

Water Tank with Ambient Temperature and 100 ppb Ozone

In the first study, 10-inch Emflon HTPFR filters were used as sterile vent filters for pharmaceutical water tank systems with 100 ppb ozone as a disinfectant in the water. The maximum air flow rate for this application of venting WFI tanks at ambient temperature was calculated to 12 m³/hour. After 6 months, the Emflon HTPFR filter passed the Water Intrusion integrity Test (WIT), and showed no deterioration in the condition of the hardware, support, drainage or media layers following a detailed visual inspection.

Water Tank with up to 40 °C and 20-100 ppb Ozone

In a further study, two Emflon HTPFR filters were used for sterile venting of pharmaceutical water system with tank volumes of 800 and 8000 liters. The estimated working volume in these applications was approximately 14 m³/day at atmospheric pressure. The ozone concentration was monitored and demonstrated to be between 20-100 ppb in the water during the usage time, with an adjustment of the ozone concentration overnight. After 25 weeks' constant venting work in an ozonated environment, both Emflon HTPFR filters passed Water Intrusion integrity tests and showed no deterioration in the condition of the hardware, support drainage or media layers.

Table 1

*Investigation Results**

Cumulated Installation time (weeks)	Tank 1 Volume: 800 liters		Tank 2 Volume: 8000 liters	
	Filter Serial Number	Integrity Test Pass/Fail	Filter Serial Number	Integrity Test Pass/Fail
10	IS6812074	Pass	IS6812153	Pass
15	IS6812074	Pass	IS6812153	Pass
20	IS6812074	Pass	IS6812153	Pass
25	IS6812074	Pass	IS6812153	Pass

* Project B-EU-CH-1341, Report # B-EU-CH-1341-IT

Summary and Recommendations

The results demonstrate that Emflon HTPFR filters have a higher degree of resistance to oxidation than Emflon II and Emflon PFR filters in vent filter systems on ozonated water tanks. Emflon HTPFR filters can be considered ideal as sterilizing-vent filters in water systems operated with:

- 20 - 100 ppb ozone in water at temperature of 20 – 40 °C for a minimum of 25 weeks' use
- 100 ppb ozone in water at ambient temperatures for a minimum of 6 months' use

For water charged with significant higher ozone concentrations or hot water installations that use ozone in addition as disinfectant, the use of Emflon PF filters (which provide full resistance to ozone) should be considered for use.

In addition to temperature and ozone concentration in the water, it is important to consider that specific installation and plant properties, as well as other operating parameters like filling and drainage rates, head volumes and steaming cycles in a water plant and tank may have further influence on the service life of sterile vent filters. Furthermore, the water quality can have an effect on the service life of the filters, as the half-life of ozone and therefore the concentration of this disinfectant is dependent on the water quality.

References

¹ P. A. Schweitzer, "Corrosion Resistance Tables," 5th edition, 2004, Marcel Dekker Inc, New York



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