CRITICAL PROCESS FILTRATION, INC.

Tank Vent Filters for USP Water Systems

Operators of pharmaceutical water systems try to keep their systems free of bacteria, even though USP systems are not required to be bacteria-free. Several methods may be used to keep bacteria and endotoxin from entering the system, including filtration of the air that enters tanks as they are emptied. This document looks at how tank vent filters fit into the array of tools used to prevent USP water system bacterial contamination.

Prevention and Remediation

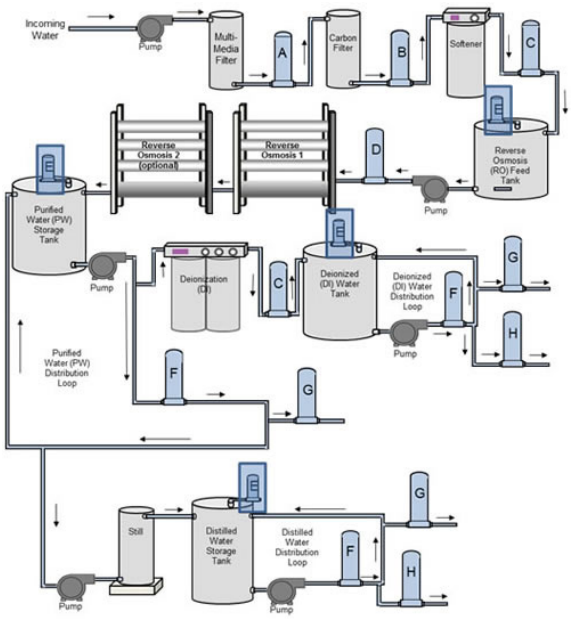
Most of the time, the old saying "an ounce of prevention is worth a pound of cure" is true. Preventing an unwanted event is usually easier than repairing whatever damage is done if the event occurs. However, in virtually all water systems, including USP water systems, it is safe to assume that BOTH prevention and remediation are needed to control bacteria.

For our purposes, we will define prevention as not allowing bacteria to enter a system. The best way to do that is to design the system using components that are operated with a minimum of maintenance and create barriers wherever there is the potential for bacterial entry from outside sources during system operation. Keeping the system components sealed and barriers in place is usually very effective. Unfortunately, almost any maintenance activity requires opening system components, exposing the interior to the atmosphere and letting bacteria enter.

Since it is almost impossible to totally prevent bacteria from entering a system, remediation steps are needed to prevent bacterial growth to unacceptable levels. Those steps usually take one of three basic forms: 1) inhibiting bacterial growth with high temperatures or high flows, 2) killing bacteria through system sanitizing and/or disinfection with heat or chemicals, 3) physically removing bacteria (filtration).

Using both prevention and remediation places multiple obstacles in the way of bacteria that might affect system compliance and potentially harm patients.

Figure 1 - Filters in a USP Water System



A- Particle Trap Filtration
B- Carbon Fines Trap
C- Resin Trap
D- RO Prefilter
E- Tank Vent Filter
F- Loop Filter
G- Cold UPDI Water POU Filter
H- Hot UPDI Water POU Filter

Application Summary

Why Tank Vent Filters?

Most tanks are not very strong structures, unless made specificaly to operate under vacuum conditions. The tanks used in most medical water systems are usually not rated for a vacuum, even if they are made of stainless steel, so operating them at elevated pressure or under a vacuum could cause structural bulging or tank implosion. Therefore, when tanks are filled or emptied, air is allowed to flow into and out of the tank to avoid pressurizing it or causing a vacuum condition. Using a vent filter allows the air inside to escape as the tank is being filled, then allows clean, bacteria-free air to enter to replace lost liquid volume when the tank is emptied.

Figure 1 on the previous page shows multiple filters to control particles and bacteria in a USP water system. The filters on the tops of tanks (marked E in the diagram) are used to filter the air directly in contact with Purified Water or Water for Injection in the tanks. The filters protect the water from bacteria and particulates in surrounding air.

Filters for Air vs Liquid

Filters used for liquid applications are usually made of materials that attract water – are 'hydrophilic' – and allow the flow of liquids through the media or membrane with low resistance. For air filtration, it is critical that the media remain dry. If the media becomes wet and the pores are filled with liquid, then the required air flow is restricted and the pressure or vacuum inside the tank can reach critical levels and cause tank failure. The various media used for air filters are 'hydrophobic' – they repel water – and resist wetting from water vapor.

Filter Options

Critical Process Filtration's hydrophobic PVDF or PTFE membrane-based cartridges and capsules are utilized for ambient temperature storage tanks. Many WFI storage tanks are maintained at elevated temperatures, requiring the use of specially designed PTFE membrane cartridges made for continuous high heat applications (70ºC to 80ºC).

All of the filters chosen need to tolerate any chemical disinfectants used in the system (bleach, peracetic acid, etc) and also should be constructed to withstand any heat sterilization or sanitization cycles (hot water or steam).

Contact Critical Process Filtration or visit us at www.criticalprocess.com for assistance in determining the best filter options for your system and for more information and access to datasheets for all of our products.

Figure 2 – Critical Process Filtration's Pleated Filters with Hydrophobic PVDF and PTFE membranes

Filter Media Options for Tank Vent Filtration in Pharmaceutical Water Systems

Process Area	Filter Application	Filter Function	Critical Process Media*
Bioburden Control and Sterilizing	Tank Vent Filtration	Prevent bacteria from entering tanks when liquid is drawn from them	PVWB, TM

*Media Codes

PVWB = High Capacity Hydrophobic PVDF Membrane

TM – PTFE Membrane

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Critical Process Filtration, Inc.
One Chestnut Street • Nashua, NH 03060
Tel: 603.880.4420 • Fax: 603.880.4536
criticalprocess.com • sales@criticalprocess.com