

Tank Vent & Process Gas Filters for Pharmaceutical Production

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All pharmaceutical production systems operators try to keep their systems free of bacteria. From filtering liquid ingredients as they are pumped into the processes to filtering final product, bacteria removal is one of the goals of every filtration process.

In addition to filtering liquids, filtration of the air that enters tanks as they are emptied and process gases as they are introduced blocks bacteria and other particles in the environment and any that may be on process gases to protect process efficiency and product quality.

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 production systems, including pharmaceutical 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. 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 bacteria from migrating from their entry point farther into the process. Those steps usually take one of three basic forms: 1) killing bacteria or 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 integrity and potentially harm patients.

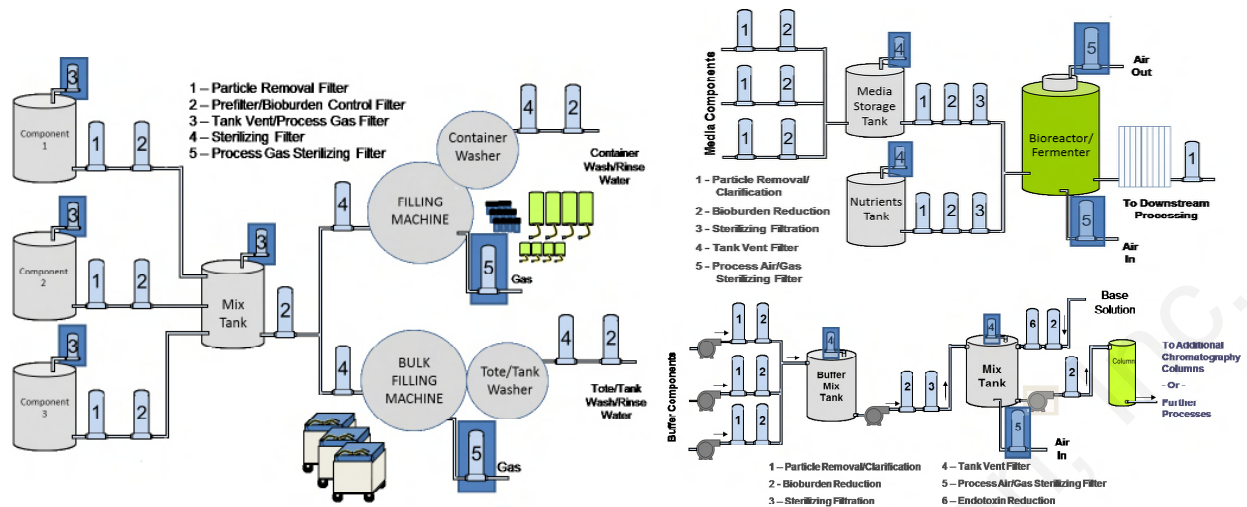


Figure 1: Vent/Process Gas Filters in Pharmaceutical Production

Why Tank Vent Filters?

The tanks used in production systems may be rated for operation under vacuum conditions but, if not, then operating at elevated pressure or under a vacuum would cause structural bulging or tank implosion. Therefore, air is allowed to flow into and out of the tank to avoid pressurizing the tank or causing a vacuum condition. As a tank is filled, the air inside is allowed to escape and avoid over-pressurization. When the tank is emptied, air (or a process gas such as nitrogen) is allowed to enter the tank to replace lost liquid volume and avoid a vacuum.

Regardless of the tank vacuum rating, allowing the flow of air or process gas into and out of the tank facilitates the efficient flow of the liquid out of or into the tank. That air or gas is filtered to remove particle and bacterial contamination.

Figure 1 on the previous page shows multiple filters to control particles and bacteria in both API and biopharmaceutical systems. The filters on the tops of tanks are used to filter the air directly in contact with ingredients, intermediates or final product in the tanks. The filters protect those liquids from bacteria and particulates in surrounding air.

Process Gas Filters

Process gas filters, like those in the housings highlighted to the right in each of the schematics in Figure 1, are also critical to the quality of pharmaceutical and biopharmaceutical production. These hydrophobic membrane filters keep particles and bacteria that may be carried by process gas from entering the process. These filters may be used if an inert gas is used for tank ventilation instead of normal air if the product in the tank is sensitive to oxygen. Another common use of process gas is for 'modified atmosphere' packaging - replacing air in bottles or other packages to keep oxygen or other atmospheric gases from the product.

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 (70°C to 80°C).

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).

Filter Options for Tank Vent & Process Gas Filtration in Pharmaceutical Production Systems

Process Area	Filter Application	Filtration Function	Media **
Bioburden Control and Sterilizing	Tank Vent/Process Gas Filtration	Prevent bacteria and other particles 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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