CRITICAL PROCESS FILTRATION, INC.

# Bioburden Control and Sterilizing Filtration for Bottled Water

Water entering a bottled water facility contains bacteria, no matter the source. Even spring water contains bacteria. While these organisms are generally not harmful to humans, they can cause off flavor or even haze in the final product if allowed to enter the final packages and grow.

Bottlers use several technologies to either remove bacteria from the bottling process or prevent bacteria from growing. Filtration is an important part of the effort to remove bacteria and produce a safe, clean product for consumers.

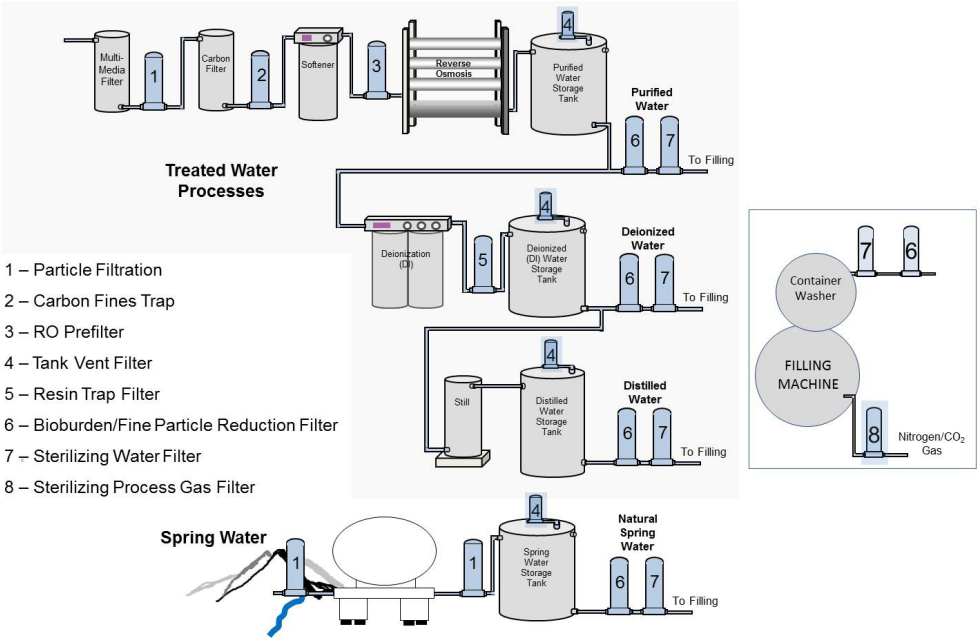
There are many forms of waterborne organisms. Harmful bacteria such as *E. coli* and *Pseudomonas* strains are common in natural sources of water. A well-known illness outbreak caused by waterborne *Cryptospridium* oocysts led to the industry taking steps to assure the microbiological safety of its products. Numerous other non-pathogenic bacteria are also common in water.

Figure 1 shows some simplified processes for multiple types of water that may be produced in a facility. Most bottled water products are actually treated municipal water that has been filtered, processed through a reverse osmosis system and bottled.

At the bottom of Figure 1 is the spring water process, which is the least complex of all. This process preserves the mineral content of the spring water as it comes from the ground while protecting the consumer from bacteria that may enter the process. Other processes may be added by the bottler, but the filtration steps are shown where they are normally located in the processes.

Waterborne organisms are often very small, and those that can survive in treated water are often smaller than those of the same type living in natural waters. For that reason, the final filters used to remove waterborne bacteria (housings marked 7 in the figure) have very small pore sizes – usually 0.10µm to 0.22µm. Because there may be a large number of particles and bacteria in high volume processes, the final filters are almost always protected by "bioburden" reduction or particle reduction filters (housings marked 6 in Figure 1). These reduce the number of particles and bacteria that the critical final filters must remove, preventing premature fouling (clogging) of the final filters.

**Figure 1 - Filters in Bottled Water Production and Packaging**




Application Summary

## Choosing the Final Filters

The most critical filters in Figure 1 are the final, "Sterilizing" filters (housings marked 7). Sterilizing filtration is defined as removing all bacteria in a fluid stream. Filters claiming to be sterilizing must be supplied with proof that they can remove organisms the size of those targeted in the user's system. The pharmaceutical industry has accepted successful removal of surrogate organisms by specific filter membranes as proof that a filter can remove organisms of similar size. The organisms are defined for each pore size rating. The testing is according to an ASTM standard (ASTM F838-05, rev 2013) that requires COMPLETE removal of all test bacteria when a filter is challenged with at least $10^7$ organisms per $cm^2$ of membrane surface area. This level of challenge is extremely unlikely in actual applications.

Critical Process Filtration provides filters tested using the ASTM standard, with 0.10µm filters challenged with *Acholeplasma laidlawii* and 0.22µm challenged with *Brevundimonas diminuta*. The sterilizing filters are supplied with a certificate of compliance stating that the filter has passed the required quality control tests.

## Protecting Sterilizing (Final) Filters

Housings marked 6 in Figure 1 hold bioburden reduction filters that remove particles and reduce the amount of organic content before the water reaches the critical final filters. These are often membrane filters designed to capture most, but not all bacteria. The filters are chosen based on the particle and organic content that must be removed.

## Preventing Contamination of Stored Water

Tank vent filters (housings marked 4 in Figure 1) are also critical to the quality of the water. These hydrophobic membrane filters keep airborne bacteria in the environment from entering tanks as they are emptied. The air in bottled water facilities may contain mold and other microorganisms, so preventing them from entering the tanks further protects product quality.

## Safeguarding Filling Operations

Filters shown on the right side of Figure 1 are not used to filter product water. They prevent contamination of the packaging by wash and rinse water during the container washing process (housings 6 and 7) and keep any bacteria that may be carried by process gases (like nitrogen or $CO_2$) from being introduced (housing 8).

**Figure 2** – Critical Process Filtration's pleated filters with multiple membrane options are used for bacteria removal.

## Filter Options

The filters chosen must be designed to function after whatever disinfection or sterilization process will be used. The organisms targeted for removal also need to be considered.

Critical Process Filtration has several filter options, as shown in the table below. These filters are available as cartridge filters and disposable capsule filters as well is in flat disc form for laboratory scale testing.

Contact Critical Process Filtration for help determining the best filter options for you.

### Filter Options for Bacteria Removal in Bottled Water Production and Packaging

| Process Area | Filter Application | Filtration Function | Critical Process Media* |
|---|---|---|---|
| Bioburden Control and Sterilizing | Bioburden Reduction | Remove most bacteria and molds | CWPS, PS, PVWL |
| | Bacteria Removal (Sterilizing) | Remove all bacteria | PS, NM |
| | Tank Vent Filtration | Prevent bacteria and other particles from entering tanks when liquid is drawn from them | TM, PVWB |
| | Process Gas Filtration | Prevent bacteria and particles in process gas from entering packages | TM, PVWB |

*Media Codes
CWPS = High Capacity PES Membrane
PVWL = High Capacity Hydrophilic PVDF Membrane
NM = Nylon 6,6 Membrane
PVWB = High Capacity Hydrophobic PVDF Membrane
PS = Polyethersulfone Membrane
TM – PTFE Membrane

Visit our website or contact us for more information and to access data sheets on all of our products.

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