

since it is closer to the final point of use (a filling machine).

FIGS. 8 and 9 illustrate a further embodiment where both process filters in series are barrier filters BF. Since barrier filters can pass air downstream, the filter housing does not require vents. This, combined with the ease with which they can be dried, results in the elimination of all venting operations and necessary vent bags along with the intermediate drain and air filters. As a result, minimal operator manipulation is required other than redirection of flow from the drain to the filling machine upon completion of the drying operation. However, pre-use integrity testing of the filters is not possible in this embodiment, since barrier filters only can be tested after wetting with isopropyl alcohol, which is not practical since verification of the complete removal of the alcohol would be required prior to introducing the product into the system. However, post-use testing can be readily performed.

FIG. 10 illustrates a further embodiment that simplifies the overall system with a unique vertical configuration of the filtration stages with F-1 configured as a barrier filter and F-2 a typical sterilizing grade hydrophilic filter. This is functionally equivalent to the embodiment shown in FIGS. 6 & 7 with the exception of the vent path for F-2. When positioned vertically and designed to allow proper flow, the air entrapped within process filter F-2 is allowed to rise through the housing and backflow through the hydrophobic portion of F-1. This is unique in that the air is passed back to the upstream side of filter F-1, which is considered to be the non-sterile side of the device. This means the air vent valve and

associated means of managing the vented air/liquid does not need to be verified for integrity; this places the vent upstream from the sterilizing membranes, which means it can be opened to the surrounding environment without breaching sterility. Venting to the upstream side of the barrier filter F-1 of FIG. 10 allows for the elimination of the vent bag shown on F-2 in FIGS. 6 and 7.

In accordance with certain embodiments, a hydrophobic membrane may be integrated into the vent (FIG. 11) such that it can vent directly to atmosphere without requiring a vent bag. After a hydrophilic membrane is wet, it will not allow air to pass through. When first introducing liquid to the system, or if a user chooses to introduce product after flushing with water but not drying, it is necessary to vent the air from the system. Historically this has been accomplished with vent ports/valves which allow the air to escape the filter housing to the environment. In this application that is considered unacceptable because opening the vent to atmosphere could breach sterility, and the final fill/filter application is conducted in a highly controlled area and allowing fluid to escape the filter would be considered a contamination of the environment. If a hydrophobic membrane is placed in line with the vent, it will maintain sterility and prevent liquid from escaping.

As compared to the current state of the art shown in FIG. 1, the configuration shown in FIG. 10 eliminates the need, during wetting, to isolate the air inlet line between F-1 and F-2, to remove the clamp normally present between F-1 and F-2 and isolate F-3 from F-2, to fill F-2 while venting out the top of F-2 and to close the vent. This is enabled by the elimination of A-1 and D-1, along with configuring F-1 and F-2 as a single housing

EXAMPLE 1

Order of operation for embodiment shown in FIGS. 1, 2 & 3:

Flushing: Close valves to isolate F-2, A-1, D-1, D-2 & OUTLET. Connect INLET to water suitable for flushing and begin flow. Open vent valves on F-1 and allow entrapped air to flow into R-1. Close vent valves on F-1 when air has been evacuated. Open valve isolating F-2 along with vent valves on F-2 and allow entrapped air to flow into R-2. Close vent valves on F-2 when air has been evacuated. Open valve isolating D-2 and flush the system as desired.

Integrity Testing: After completing the flushing operation, close the valve isolating F-1 from F-2. Open the valve isolating A-1 and follow standard procedures for integrity testing F-2. F-1 is tested by opening the valve isolating D-1 and integrity testing through the INLET port of the system.

Drying: After completing the integrity test operation, F-1 and F-2 can be dried independently by air pressure above the membrane bubble point to INLET for F-1 and A-1 for F-2.

Filtration: Close valves to isolate F-2, A-1, D-1, D-2 & OUTLET. Connect INLET to product which is to be filtered and begin flow. Open vent valves on F-1 and allow entrapped air to flow into R-1. Close vent valves on F-1 when air has been evacuated. Open valve isolating F-2 along with vent valves on F-2 and allow entrapped air to flow into R-2. Close vent valves on F-2 when air has been evacuated. Open valve isolating OUTLET and conduct filtration operation.

Example 2

Order of operation for embodiment shown in FIGS. 4 & 5:

Flushing: Close valves to isolate F-2, D-2 & OUTLET. Connect INLET to water suitable for flushing and begin flow. Open vent valves on F-1 and allow entrapped air to flow into R-1. Close vent valves on F-1 when air has been evacuated. Open valve isolating F-2. Open valve isolating D-2 and flush the system as desired.

Integrity Testing: After completing the flushing operation, F-1 is integrity tested through the INLET port following standard procedures. F-2 is not pre-use tested.

Drying: After completing the integrity test operation, F-1 and F-2 can be dried simultaneously by applying air pressure to the INLET port such that it exceeds the bubble point of F-1.

Filtration: Close valves to isolate F-2, D-2 & OUTLET. Connect INLET to product which is to be filtered and begin flow. Open vent valves on F-1 and allow entrapped air to flow into R-1. Close vent valves on F-1 when air has been evacuated. Open valve isolating F-2. Open valve isolating OUTLET and conduct filtration operation.

Example 3

Order of operation for embodiment shown in FIGS. 6 & 7:

Flushing: Close valves to isolate D-2 & OUTLET. Connect INLET to water suitable for flushing and begin flow. Open vent valves on F-2 and allow entrapped air to flow into R-2. Close vent valves on F-2 when air has been evacuated. Open valve isolating D-2 and flush the system as desired.

Integrity Testing: After completing the flushing operation, F-2 is integrity tested through the INLET port following standard procedures. F-1 is not pre-use tested.

Drying: After completing the integrity test operation, F-1 and F-2 can be dried simultaneously by applying air pressure to the INLET port such that it exceeds the bubble point of F-2.

Filtration: Close valves to isolate D-2 & OUTLET. Connect INLET to product which is to be filtered and begin flow. Open vent valves on F-2 and allow entrapped air to flow into R-2. Close vent valves on F-2 when air has been evacuated. Open valve isolating OUTLET and conduct filtration operation.

Example 4

Order of operation for embodiment shown in FIGS. 8 & 9:

Flushing: Close valves to isolate D-2 & OUTLET. Connect INLET to water suitable for flushing and begin flow. Open valve isolating D-2 and flush the system as desired.

Integrity Testing: pre-use testing is not conducted with this configuration.

Drying: After completing the integrity test operation, F-1 and F-2 can be dried simultaneously by applying air pressure to the INLET port.

Filtration: Close valves to isolate D-2 & OUTLET. Connect INLET to product which is to be filtered and begin flow. Open valve isolating OUTLET and conduct filtration operation.

What is claimed is:

1. A filtration system in a manufacturing process to yield product, the filtration system comprising:

a network defining a fluid process stream, said network having one or more inputs for introducing fluid into said process stream, and one or more outlets for discharging fluid from said process stream;

a first process filter within said fluid process stream;

a second process filter within said process stream, said second process filter being positioned in series with said first process filter and downstream thereof;

wherein at least one of said first process filter and said second process filter is a barrier filter comprising, within a common enclosure, at least one hydrophilic filter membrane and at least one hydrophobic filter member and wherein the first and second process filters filter the fluid in the process stream that yields said product.

2. The filtration system of claim 1, wherein said barrier filter comprises a plurality of hydrophilic membranes and a plurality of hydrophobic membranes, and wherein said hydrophilic membranes are interspersed between said hydrophobic membranes.

3. The filtration system of claim 1, wherein said first process filter is said barrier filter.

4. The filtration system of claim 1, wherein said second process filter is said barrier filter.

5. The filtration system of claim 1, wherein both said first and said second process filters are barrier filters.

6. The filtration system of claim 1, wherein said fluid process stream is devoid of an air filter between said first and second process filters.

7. The filtration system of claim 1, wherein said fluid process stream is devoid of a drain filter between said first and second process filters.

8. A filtration train for a process stream for filtering fluid, said process stream having an inlet and an outlet for discharging a desired product from said process stream resulting from said filtration train, said filtration train being in fluid communication with said inlet and said outlet; said filtration train comprising a first process filter and a second process filter positioned in series with said first process filter and downstream thereof; wherein at least one of said first process filter and said second process filter is a barrier filter comprising, within a common enclosure, at least one hydrophilic filter membrane and at least one hydrophobic filter member, and wherein the first and second process filters filter the fluid in the process stream that yields said desired product.

9. The filtration train of claim 8, wherein said barrier filter comprises a plurality of hydrophilic membranes and a plurality of hydrophobic membranes, and wherein said hydrophilic membranes are interspersed between said hydrophobic membranes.

10. The filtration train of claim 8, wherein said first process filter is said barrier filter.

11. The filtration train of claim 8, wherein said second process filter is said barrier filter.

12. The filtration train of claim 8, wherein both said first and said second process filters are barrier filters.

13. The filtration train of claim 8, wherein said fluid process stream is devoid of an air filter between said first and second process filters.

14. The filtration train of claim 8, wherein said fluid process stream is devoid of a drain filter between said first and second process filters.