

How to prevent vent filter integrity test failures on hot WFI storage tanks.

Customer:

A global biopharmaceutical company focused on developing life changing therapies.

Application:

Pharmaceutical

Hall Pyke product:

COR-PFA all PTFE 0.2

Customer issue:

The customer has a 0.2 micron sterile vent filter installed on the wash tank of their CIP skids. When the filter is tested for integrity, using the WIT test method, the filter consistently fails.

The current filter is a 0.2 micron PTFE high temperature, hydrophobic membrane filter, made up as follows:

Membrane: PTFE

Hardware: Polypropylene

Support and drainage layers: (PPS) polyphenylene sulphide.

Application Overview:

Venting applications require careful management of condensate on the vent filter to maintain a sufficient level of gas flow, not only during use, but also during steam sterilization. Water vapor can condense on a vent filter membrane during use if the fluid in the tank is water based and the temperature of the filter is lower than the dew point of the fluid in the tank.

In most applications the fitting of a heating jacket will resolve this issue by maintaining the temperature of the vent filter and housing slightly above the dew point of the liquid in the vessel. This should prevent the formation of condensate on the filter, thus preventing the filter from blocking and being damaged due to excessive differential pressure.

Hall Pyke Solution:

After a number of site visits it was observed, that shortly after the wash tank started to fill with hot WFI, the flow of steam from the tank passing through the sterile vent filter ceased, indicating that the filter was blocked.

The filter was removed and brought back to our lab where we carried out a reverse bubble point test, the results confirming filter failure by extensive bubbling @ 150mbar.

The lab deconstructed the filter for further inspection, the membrane was shown to have been damaged, evident by the collapsing of the pleat pack. This indicated that the max differential pressure had been exceeded in the reverse flow direction, again an indication that the filter was blocked, thus confirming the pressure when filling the tank exceeded the design operating parameters of the filter, causing the filter to fail.

We believe condensate was able to penetrate the pores of the drainage layer and possibly even the membrane.

Vapour at 90°C has a much lower surface tension and makes wetting of a hydrophobic membrane a lot easier. The wetting of the membrane created enough of a blockage to exceed the max differential of the filter, thus damaging the membrane and affecting the integrity.

Our solution is to use our COR-PFA filter, which has an all-fluoropolymer construction.

We installed our filter and carried out water intrusion tests every 4 weeks, for six months, without any failures.

