



Biotech

## Technical Regulatory Topic

---

### **Meeting Regulatory Requirements for Vent Filtration on Water for Injection (WFI) Tanks**

Document Number: USTR 3441  
Revision Number: 1.0  
Date: 04-JAN-2021

# 1 Introduction

Water systems for the production, storage, and distribution of purified water or WFI remain critical points in pharmaceutical production plants. A key concern of regulatory authorities is the installed vent filter on high purity water-holding tanks. This document provides Pall's technical recommendations to meet current regulatory requirements and to ensure:

- Sterile protection of the tank utilizing Emflon® HTPFR or PFR vent filters
- Built-in drainage utilizing Pall Advanta™ liquid and gas filter housings
- Prevention of condensate utilizing Pall Advanta housing trace heaters
- Reliable water intrusion testing utilizing the Palltronic® AquaWIT filter integrity test system

## 2 Regulatory Guidelines

The FDA's Guide to Inspections of High Purity Water Systems (1993)<sup>1</sup> recommends regular filter testing and prevention of condensate formation in vent filters on high purity water-holding tanks.

The guide states: "VII. HOLDING TANK - In hot systems, temperature is usually maintained by applying heat to a jacketed holding tank or by placing a heat exchanger in the line prior to an insulated holding tank. The one component of the holding tank that generates the most discussion is the vent filter. It is expected that there be some program for integrity testing this filter to assure that it is intact. Typically, filters are now jacketed to prevent condensate or water from blocking the hydrophobic vent filter. If this occurs (the vent filter becomes blocked), possibly either the filter will rupture or the tank will collapse. There are methods for integrity testing of vent filters in place. It is expected, therefore, that the vent filter be located in a position on the holding tank where it is readily accessible."

In a similar manner, the European GMP Guide<sup>2</sup> calls for regular testing of vent filters used in applications such as vents on water tanks. Additionally, the ASME<sup>3</sup> Bioprocessing equipment guide (ASME BPE 2012<sup>3</sup>) defines how equipment must be designed and installed to be classed as hygienic. Chapter SD-5.2.1 states that "The filter housing shall be designed to allow for complete venting and draining. Liquid tee-type filter housings should be installed vertically, and vent type in-line filter housings should be installed vertically with the condensate/drain port directed downward". Furthermore, it states: "Vent filters for hot process services should be heat traced or steam jacketed".

Figure 1 and Figure 2 show recommended arrangements for single/dual vent filter installations on hot WFI tanks.

---

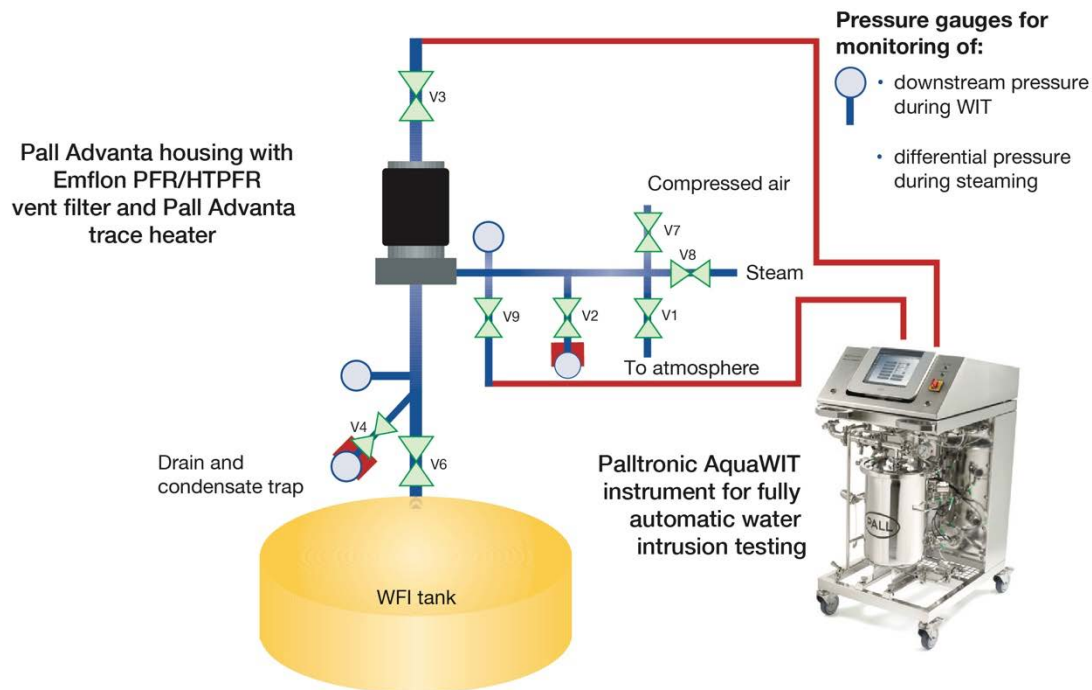
<sup>1</sup> U.S. Food & Drug Administration, *Guide to Inspections of High Purity Water Systems*.  
<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/high-purity-water-system-793>, accessed 8 December 2020.

<sup>2</sup> EudraLex – *The Rules Governing Medicinal Products in the European Union*. Volume 4, Annex 1.  
[https://ec.europa.eu/health/documents/eudralex/vol-4\\_en](https://ec.europa.eu/health/documents/eudralex/vol-4_en), accessed 04 January 2021.

<sup>3</sup> The American Society of Mechanical Engineers. *Bioprocessing Equipment*, 2012.  
[https://www.asme.org/codes-standards/find-codes-standards/bpe-bioprocessing-equipment-\(1\)?productKey=A1431V:A1431V](https://www.asme.org/codes-standards/find-codes-standards/bpe-bioprocessing-equipment-(1)?productKey=A1431V:A1431V), accessed 04 January 2021.

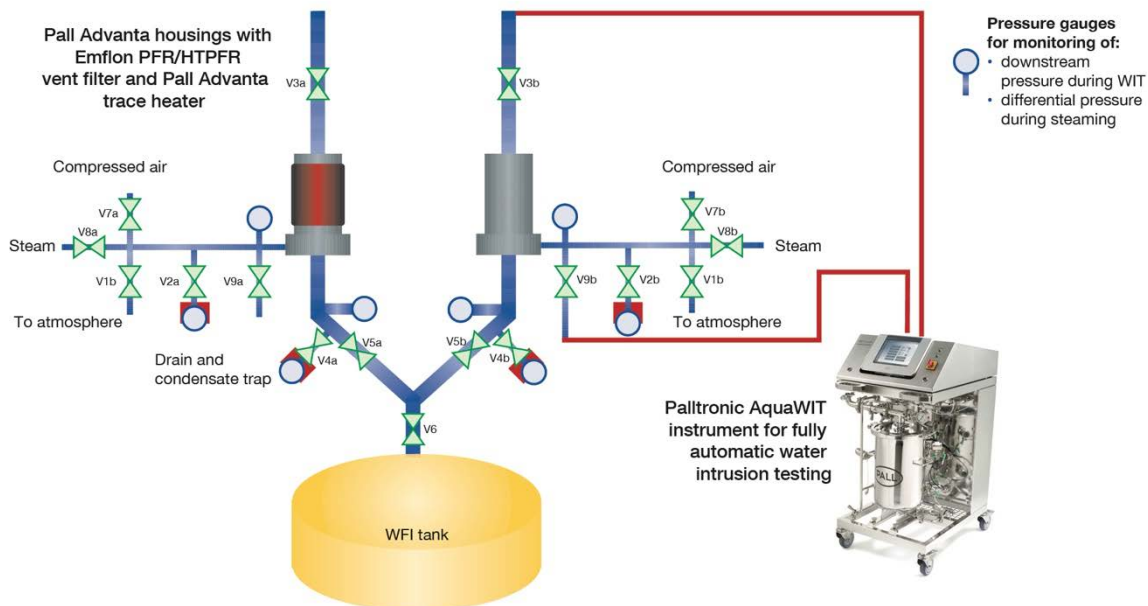
**Figure 1.**

*Vent filter installation for hot WFI tanks. A single installation without continuous use of the WFI tank during water intrusion testing (WIT) of the vent filter*



**Figure 2.**

*Vent filter installation for hot WFI tanks. A double installation is recommended to allow continuous use of the WFI tank and water intrusion testing (WIT) of the vent filters*



### 3 Conclusion

Condensate blinding of high-flow sterile filters such as Emflon HTPFR or Emflon PFR filters can be avoided by using Pall Advanta housings together with the Pall Advanta trace heater and is simple to deploy. The Palltronic AquaWIT filter integrity test system can be used to automatically perform water intrusion tests on tank vent filters, to assure that these critical filters still have sterilizing capability during long-term operation, or after steam sterilization.

For more information, please see Pall's Application Note USD2121a.



#### Corporate Headquarters

Port Washington, NY, USA  
+1.800.717.7255 toll free (USA)  
+1.516.484.5400 phone

#### European Headquarters

Fribourg, Switzerland  
+41 (0)26 350 53 00 phone

#### Asia-Pacific Headquarters

Singapore  
+65 6389 6500 phone

---

Visit us on the Web at [www.pall.com/biotech](http://www.pall.com/biotech)

---

Contact us at [www.pall.com/contact](http://www.pall.com/contact)

---

#### International Offices

Pall Corporation has offices and plants throughout the world in locations such as: Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, India, Indonesia, Ireland, Italy, Japan, Korea, Malaysia, Mexico, the Netherlands, New Zealand, Norway, Poland, Puerto Rico, Russia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, the United Kingdom, the United States, and Venezuela. Distributors in all major industrial areas of the world. To locate the Pall office or distributor nearest you, visit [www.pall.com/contact](http://www.pall.com/contact).

The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

© 2021 Pall Corporation. The Pall logo, Pall, Emflon, Pall Advanta and Palltronic are trademarks of Pall Corporation. ® indicates a trademark registered in the USA and TM indicates a common law trademark.

♦ ASME is a trademark of The American Society of Mechanical Engineers.  
Filtration. Separation. Solution is a service mark of Pall Corporation.

**Filtration. Separation. Solution. <sup>SM</sup>**