BIOTECH

Technical Regulatory Topic

USTR 3699

Troubleshooting Guide for Water Intrusion Test (WIT) Failures

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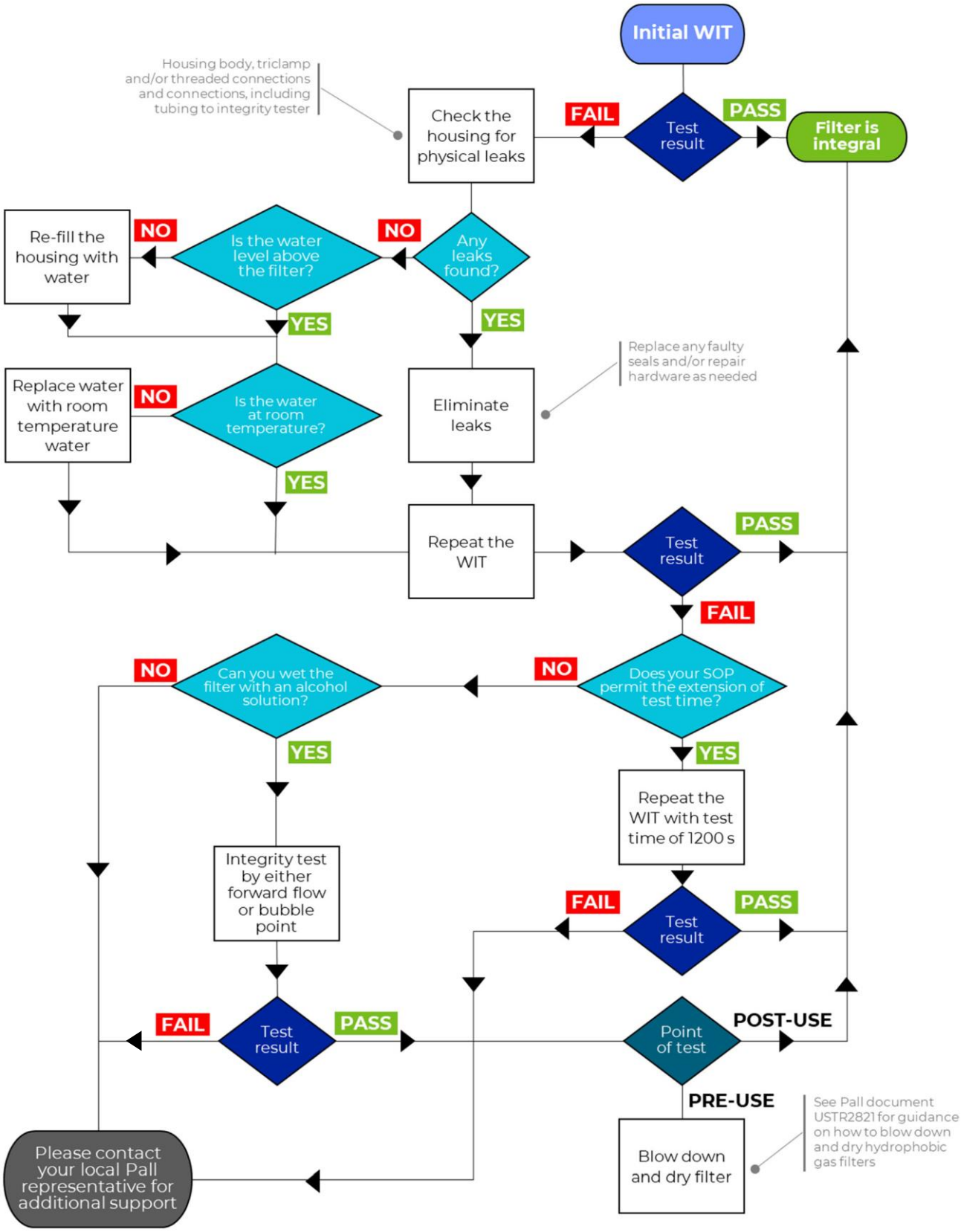
Sterilizing-grade gas filters play a critical role in the maintenance of sterile boundaries in pharmaceutical processes by preventing the movement of microorganisms into or out of systems whilst allowing pressure equilibration as fluids fill or empty vessels. Such filters incorporate hydrophobic membranes to prevent wetting during operation in humid environments, which would cause a subsequent loss of filter performance. Despite being an intentional design characteristic of sterilizing-grade gas filters, the membrane's hydrophobicity makes filter integrity testing more challenging as the widely accepted bubble point and forward flow tests rely upon a filter membrane being wetted out to establish the filter's integrity. One method employed to overcome the non-wettability of these hydrophobic membranes with water is to use an organic solvent, such as isopropyl alcohol, mixed with water. This does, however, introduce a potential contaminant to the system meaning the tests become unsuitable for performance *in-situ*. It also means that, if the test is performed pre-use, a flushing and drying period must be implemented, adding time and complexity to filter installation.

An alternative strategy is to employ the water intrusion test which utilizes the hydrophobicity of the filter membrane to establish the filter's integrity. In a WIT, only water and a gas, such as air or nitrogen, are used as test media meaning that the filter does not need to be flushed and dried post-test. Furthermore, the WIT only requires the non-sterile side of the filter to be exposed to these test media. This means that the filter can be tested *in-situ* as only a negligible amount of water will cross the membrane of any integral filter into the system.

Studies have shown that the basis of the WIT is the evaporative loss of water through the filter membrane [1]. A number of factors such as water temperature and pressure stabilization in time, have been shown to influence the evaporation of water through the membrane during a WIT. These additional losses could be responsible for false failures of the WIT. Care needs to be taken to avoid incorrect assessment of the filter integrity and to identify these false failures using the WIT [2]. The decision tree shown in this document (see Figure 1) establishes a logical procedure that an end-user can consult when utilizing the WIT as their integrity test method for sterilizing-grade gas filters.

Figure 1

Decision tree



References

[1] R. Jaenchen *et al*, "USTR 2047 Studies on the Theoretical Basis of the Water Intrusion Test (WIT)," Pall Corporation, 2002.

[2] I. Johnson and M. Cardona, "USD 3033 Best Practices for Successful Integrity Testing Using the Water Intrusion (WIT) Method," Pall Corporation, 2015.

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