



Sterile Filter Validation Testing

PRI Bio offers sterile filter integrity testing and validation service for your sterile filter membrane systems, to ensure proper functionality for the safety of your staff and the environment. PRI Bio's technicians are Pall factory-trained and utilize the Palltronic® Flowstar integrity testing instrument to perform non-destructive integrity testing of your membrane filter assemblies. Testing capabilities include water intrusion test, forward flow test, bubble point test, and combined forward flow and bubble point test.

Upon completion of the test, electronic and paper reports are generated for documentation and regulatory compliance indicating a status of "Pass" or "Fail."

Benefits:

- Validation that filter meets the manufacturer's specifications
- Validation that filter is installed correctly
- Validation of filter assembly integrity
- Validation that filter is proper grade for application
- Test report documentation to comply with regulatory requirements
- Peace of mind that biosafety concerns are met

Various Test Methods:

Water Intrusion Test:

The Water Intrusion test is widely utilized in pharmaceutical manufacturing and research laboratories to perform inline integrity testing of sterilizing grade gas filters with hydrophobic membranes. The Palltronic Flowstar IV instrument is specially designed and validated to perform this very sensitive test.

Forward Flow Test:

The Forward Flow test is the filter integrity test that is most common in pharmaceutical manufacturing. All major filter suppliers recommend the Forward Flow test as the method of choice for integrity testing of filter cartridge or capsule assemblies. The Palltronic Flowstar IV instrument performs the Forward Flow test quickly and with extreme accuracy. The volume dosed flow meter can perform a Forward Flow test in a range of 0.1 to 1000 mL/min within minutes and with an accuracy of 0.1 mL/min or 3%.

Bubble Point Test:

The Palltronic Flowstar IV integrity test instrument can determine the Bubble Point of a filter. The gas flow rate is measured at increasing pressure steps, and the Bubble Point is the transition of diffusive gas flow through wetted filter pores to bulk gas flow through de-wetted filter pores.

Combined Forward Flow and Bubble Point Test:

The instrument can also determine the Forward Flow and Bubble Point value in a single test. The test procedure has been refined to shorten test times of the combined test without compromising the accuracy of the result. Leak Test and Pressure Decay Test The leak test can be used to test for leaks in filter systems or processing systems. It is not an integrity test, since there is no correlation to bacterial retention. The leak rate can be measured either as pressure drop (mbar/min), using the Pressure Decay Test or as flow rate (mL/min), using the Leak Test function of the instrument.

