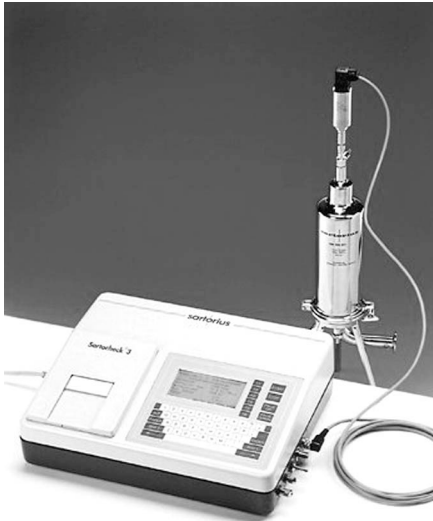


Product Integrity Tests



Description

The Product Integrity Test is a non-destructive method of determining the presence of defects in a filter.

The commonly used tests for hydrophilic filters are:

- Bubble point
- Diffusive flow
- Pressure- hold (decay)

The bubble point test is a measure of the pressure necessary to cause a flow of gas through a wetted membrane and is related to the largest pores in the filter membrane. Bubble points can be directly related to bacterial retention.

The diffusive flow test is an expression of Fick's law of diffusion which is a function of the filter's total porosity and the solubility of gas (usually air) in the wetting fluid.

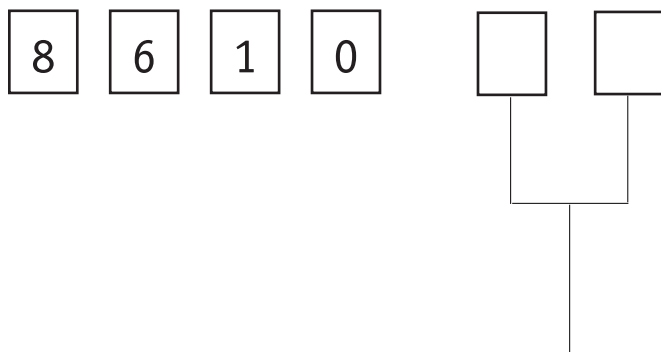
The pressure hold test is a variant on the diffusive flow measurement and is best applied to cartridge filters in housings. Air pressure is applied on the up-stream side of the filter, this is then closed off and the air lost from the upstream side of the housing is measured over time.

Testing by Sartorius can be performed on-site by qualified technical specialists or at one of our validation laboratories. We provide automated, reproducible results in water, alcohol or the Customer's product formulation.

Test Specifications:

Product Integrity Tests establishes the Minimum Bubble Point or Diffusive Flow Values using The Pharmaceutical Formulation. Tests involve the use of small area pleated devices and are based on custom protocols.

Ordering Guide:



Test Description

- 20 = Product Integrity Test - Establishes the product-wet integrity test value (minimum bubble point or diffusive flow), using customer product that is non-complex. Tests involve the use of small area pleated devices up to 6 hours
- 21 = Product Integrity Test - Establishes the product wet integrity test value (minimum bubble point or diffusive flow), using customer product that requires special handling or is complex. Tests involve the use of small area pleated devices for up to 24 hours

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