Basis Validation for

PU / PUR Sterile filter elements

CONTENT

EINLEITUNG

The PU / PUR sterile filter element was developed for the safe sterile filtration of compressed air and other process gases. The filter element fulfills the high requirements in food (breweries, dairies, soft drinks) and pharmaceutical industries and works reliable even under extreme operating conditions.

Based on the patented binderfree micro fibre medium made of borosilicate, this depth type filter realises high particle holding capacity and long service life. The depth filter medium is non-fibre-releasing and complies to the FDA requirements (Food and Drug Administration 21CFR 211.72 latest edition and EC/1935/2004). Several layers of the glass fibre medium are embedded in stainless steel supports and bound to stainless steel end caps. The sturdy stainless steel construction permits over hundred (100) possible sterilisation cycles at specified conditions and withstands high differential pressures in both flow directions.

PU / PUR sterile filter elements guarantee a safe and reproducable production.

This validation guide has been prepared in order to emphasise and confirm the special filtration characteristics. It includes performance data, microbiological retention, testability and steam sterilisation. A high quality standard is guaranteed for all produced filters.

QUALITY ASSURANCE

Quality of products

Product quality is of the highest importance to us. Sterile filter elements are manufactured under strict quality control guidelines. Test reports are established on raw materials as well as during production.
Before being packed each sterile filter is controlled and integrity tested according to EN 1822 using an aerosol impact test.

Product traceability

Each filter element achieves an unique Lot ID engraved on the element cap. This number allows to recall the production of this filter element up to the used raw materials.

The various described test methods are ba- sed on and made in accordance to regulations, described and made public by EP, HIMA, FDA, ISO and ASTM D 2986-91.

Each packing unit is marked with the Article No. and Lot ID and comes together with the operation manual for sterile filter elements.

PRODUCT SPECIFICATION

Application

PU / PUR sterilefilter elements are designed for use within pharmaceutical applications, and for sterilisation duties, food and beverages, as defined by the HIMA regulations. All elements achieve their designed specification.

Materials of construction

See separate material certificate.

Further product document

- Operation manual for sterile filters”
- Process filters“
- Operation manual for housings”
- Guideline for sterilisation of sterile filters

VOLUME FLOW

Product claim

Air flow rates of a 10 inch PU / PUR filter element by different conditions. Normal condition (1.013 bar; 20 °C; 70 % rel. Humidity).

Test procedures

Purpose: To determine the correlation between the flow rate and the differential pressure for elements installed in various housings (AFE, Donaldson, Ultrafilter, Parker, etc.).

Materials

1. Clean, dry air (0,2 µm), 1-7 x 105 Pa
2. Pressure regulator, 1-7 x 105 Pa
3. Two pressure gauges
4. Flow meter
5. Test filter element
6. Test filter housing

Method

Differential pressures are measured at several different flow rates. At the end of the test, repeat initial flow rates to check for consistency.

MAXIMUM DIFFERENTIAL PRESSURE

Product claim

The PU / PUR sterile filter element withstand a maximum differential pressure of 5 bar for 24 hours and maintain integrity.

Test procedure

Purpose: Determining the ability of a filter cartridge to withstand continuous differential pressure whilst maintaining the same integrity.

Materials

1. Liquid pump for pressures up to 7 bar
2. Water reservoir
3. Test filter housing
4. A.C. Fine Test Dust
5. Test filter element
6. Pressure Gauge

Method

A.C. Fine Test Dust is added to the water flow until a differential pressure of 5 bar is reached. This is held for 24 hours. The integrity test is carried out before and after the test procedure.

BACTERIA RETENTION DESTRUCTIVE

Product claim

The PU / PUR filter element is a sterilising grade filter, showing no penetration.

Test procedure

Purpose: To validate the ability of the PU / PUR sterile filter element in providing sterile filtrate. The filter was exposed to a single layer of the test bacteria (most penetrating particles) Brevundimonas diminuta with a size of 0.2 µm.

Materials

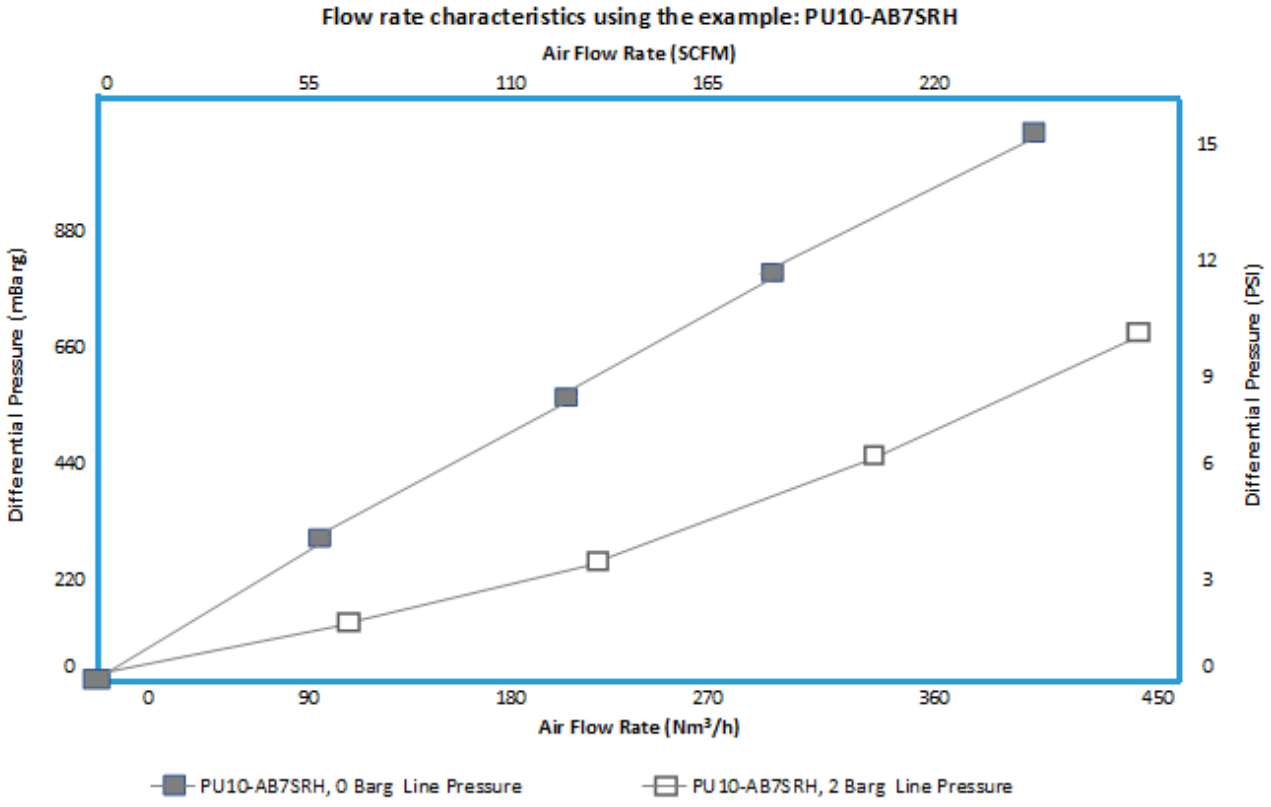
1. PU / PUR test filter element
2. Stainless steel filter housing
3. Bacteria suspension atomiser
4. Test organism Brevundimonas diminuta
5. Sanitary valves
6. Membrane filter for analysis
7. Test analysis equipment

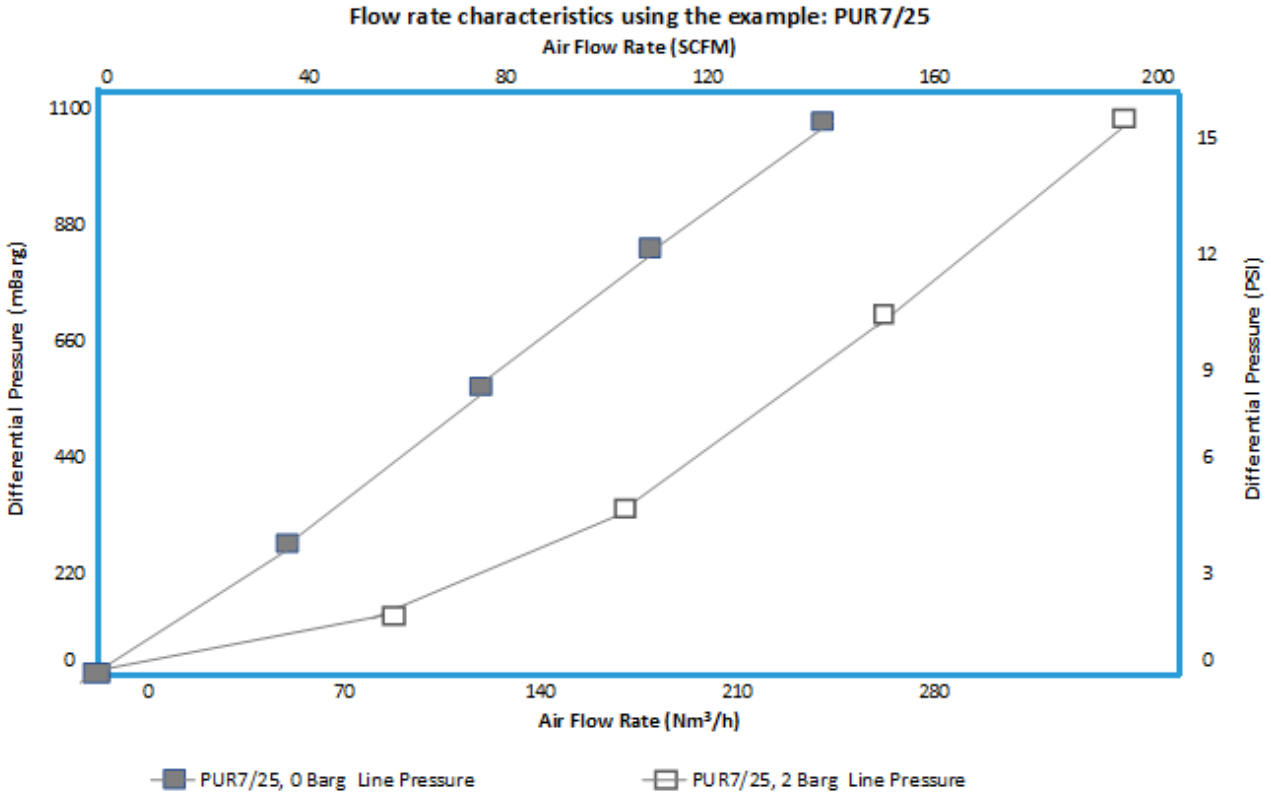
Method

The PU / PUR sterile filter elements were challenged with a defined bacteria for a maximum of 24 hours. Down stream analysis occurred with nutrient - on after incubation. The test was conducted at nominal air flow and temperature conditions.

Flow rate values

The flow value oft he filter cartridges were determined for three different filter batches at an inlet pressure of 0 bar and 2 bar.
The diagrams below show the average values.





STERILIZATION AUTOCLAVE

Product claim

The PU / PUR sterile filter elements withstand a minimum of 200 sterilization cycles in an autoclave. 121°C, 2,1 bar for 30 minutes (250 °F). The cumulative sterilization time is at least 50 hours.

Test procedure

Purpose: To provide a method for sterilization of the filter assembly with saturated steam in an autoclave.

Materials

1. PU / PUR sterile filter element
2. pressure gauge
3. thermo couples
4. autoklave

Method

The PU / PUR serile filter element is heated up to 121 °C for 30 min. with saturated steam, cooled down to ambient temperature and heated again. Every test cycle includes an integrity test with the FTC-Test (DOP Test with Parafin), acc. to EN 1822 and ASTM D 2986-91.

STERILIZATION IN-LINE

Product claim

The PU / PUR sterile filter elements withstand a minimum of one hundred (100) in-line sterilization sycles with purifed, saturated steam:

In-line sterilization
142°C for 30 minuts

Test procedure

Purpose: The sterilisation of the PU / PUR sterile filter element with saturated In-Line steam.

Materials

1. PU / PUR test filter element
2. Stainless Steel filter housing with pressure gauge
3. Sanitary valves
4. Steam generator
5. Steam filter, sintered stainless steel, pore size 1 micron
6. Saturated steam, filtered down to 1 micron

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Method

The PU / PUR filter element is slowly heated In- Line up to 142 °C for 30 minutes, cooled down to ambient temperature and heated again. Slowly the steam enters the filter via a pressure regulator. The integrity of the filter element is tested with the FTC measurement after every sterilisation cycle, according to ASTM D 2986-91 and DIN EN 1822.

The test results of the integrity test shows that the sterile filter, if sterilised (steamed) according to the defined conditions, which will guarantee more than 100 sterilisation cycles.

The lifetime of filter elements is influenced by the process conditions, the use of oxidation additives, cleaning- and any other kinds of solvents. Hence, the lifetime will vary depending on the application.

INTEGRITY TEST non-destructive aerosol challenge

Produkt claim

The PU / PUR sterile filter elements are tested for integrity using the aerosol impact test in accordance with EN 1822. The test agent is liquid paraffin. Minimum FTC-efficiency: 99,99998% (retention rate).

Test procedure

Purpose: To determine the filter integrity using the aerosol impact test (with liquid paraffin).

Material

1. Test filter housing
2. Test filter element (6 of each)
3. Clean, dry air
4. Valairdata Test equipment

The Valairdata equipment is easy to operate. An in-built software checks all important functions. The Valairdata aerosol test device is a validated test method that correlates directly with the bacterial challenge test.

Method

During testing, the VALAIRDATA applies a single layer of a test aerosol of the most critical particle size of 0.1 to 0.3 µm (MPPS: Most Penetrating Particle Size) to the upstream side of a sterile filter element.
If test aerosols are able to penetrate the filter, they are returned from the downstream side of the filter to the detector comb of the VALAIRDATA, where they are then detected and attracted with the aid of a laser particle counter.

Correlation to aerosol bacterial challenge test

$$LRV = \frac{\text{Log10 quantity of organism}}{\text{Number of organism after filtration}}$$

CHEMICAL COMPATIBILITY

Product claim

The PU / PUR sterile filter elements materials are stainless steel, filter media and potting material. The element is compatible with all natural gases and most toxic and aggressive media. The compatibility will decrease if there is an increase in the aggressive media concentration.

Method

1. Determine and record the following data fort he filter element:
   - integrity test
   - dimensions
   - flow rates
   - appearance
2. Complete flow through the filter element with the test gas. Immerse the filter element in the test fluid.
3. Testing procedure for 48 hours.
4. Determine and record the data listed in step 1.
5. Data Interpretation:

R = Resistant
No change was observed in performance, physical properties or dimensions.

LR = Limited Resistant
Minor changes in physical properties or dimensions of the cartridge filters were observed filter integrity was not altered.

NR = Not Resistant
The cartridge was found to be unsuitable in the test medium.

Material

1. PU / PUR test filter element
2. Pressure gauge
3. Thermo element
4. Autoklav

Test procedure

Purpose: To determine the compatibility of filter elements with solvents, acids and bases.

5. O-Ring material was silicone.
   Different O-Ring materials may increase the chemical compatibility of the filter cartridge.

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