Basic-Validation for PU / PUR Sterile Filter-Elements

Contents

Introduction

The PU / PUR sterile filter element was developed for the safe sterile filtration of compressed air and other process gases.
This filter element fulfils all requirements for the food (breweries, dairies, soft drinks manufacturers) and pharmaceutical industries and is also very reliable under orduous operating conditions.
Based on the binder-free microfibre medium made of borosilicate. This depth filter achieves a high particle holding capacity and long service life. The depth filter medium is non-fibre-releasing and therefore complies with FDA requirements (Food and Drug Administration 21CFR 211.72 latest edition and EC/1935/2004).
Numerous layers of filter media are embedded between stainless steel support cylinders and bonded to stainless steel end caps. The robust stainless steel construction allows over one hundred (100) possible sterilisation cycles under specified conditions and withstands high differential pressures in both flow directions.

PU / PUR-Sterilefilterelements guaranteed a safety and reproducible Production Result.

This validation guide was created to emphasise and confirm the special filtration properties of the filter elements. It contains performance data, specifications for microbiological retention, testability and steam sterilisation. A high quality standard is guaranteed for all filters produced.

QUALITY ASSURANCE

Quality of the Products

Product quality is of the utmost importance to us. Sterile filter elements are manufactured under strict quality control guidelines in Germany. Test reports are drawn up both on the raw materials and during the manufacturing process.
Production is carried out in accordance with the DIN ISO 9000ff quality standard
Before packaging, each sterile filter element is inspected and tested for integrity in accordance with EN 1822 using an aerosol challange test.

Product traceability

Each filter element produced is given a unique batch ID, which is engraved on the element cap. This number makes it possible to trace the production of this filter element back to the raw materials used.
The various test methods used are described and published in accordance with the regulations of EP, HIMA, FDA, ISO and ASTM D 2986-91.
Each packaging unit is labelled with the article no. and the batch ID and is provided together with the delivery.

PRODUCT SPECIFICATION

Applications

PU / PUR sterile elements are designed for use in pharmaceutical applications and for sterilisation tasks in the food and beverage industry in accordance with HIMA regulations. All elements achieve their intended specification.

Materials of construction

See separate material certificate.

Further product documents

- Operating instructions for "housing"
- Operating instructions for "Process-Filter“
- Operating instructions for "Sterilfilter”.
- IOMI for Sterilisation of Filter Elements

VOLUME Flow

Product requirement

Air flowrate of a 10-inch PU / PUR filter element under various conditions. Normal condition (1.013 bar; 20 °C; 70 % relative humidity).

Test method

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

Equipment

1. 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

The differential pressures are measured at different flow rates. At the end of the test, the initial flow rates are repeated to check consistency.

MAXIMUM DIFFERENTIAL PRESSURE

Product requirement

The PU / PUR sterile element withstands a maximum differential pressure of 5 bar for 24 hours and retains its integrity.

Test method

Purpose: Determination of the ability of a Filterelement, to withstand a continous differential pressure while maintaining integrity..

Equipment

1. 1. compressor for pressures up to 7 bar
   2. air reservoir
   3. test filter housing
   4. AC fine test dust
   5. test filter element
   6. pressure gauge

Method

AC fine test dust is added to the air flow until a differential pressure of 5 bar is reached. This is maintained for 24 hours. The integrity test is carried out before and after the test procedure.

BACTERIA RETENTION DESTRUCTIVE

Product requirement

The PU / PUR sterile Filter-Element is a filter that has no microbiological penetration.

Test method

Purpose: To validate the ability of the PU / PUR sterile filter element to provide 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.

Equipment

1. 1. PU / PUR test filter element
   2. stainless steel filter housing
   3. bacteria suspension atomizer
   4. test bacteria Brevundimonas Diminuta
   5. sanitary valves
   6. membrane filter for the analysis
   7. equipment for the test analysis

Method

The PU / PUR sterile filter elements were exposed to a defined bacteria for a maximum of 24 hours. The downstream analysis was carried out by incubation on a nutrient agar. The test was carried out under nominal air flow and temperature conditions.

STERILISATION AUTOCLAVE

The PU / PUR sterile filter elements can withstand at least 200 sterilisation cycles in an autoclave. 121°C, 2.1 bar for 30 minutes (250 °F). The cumulative sterilisation time is at least 50 hours.

Test method

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

Equipment

1. 1. PU / PUR sterile filter element
   2. pressure gauge
   3. thermocouples
   4. autoclave

Method

The filter element is heated to 121 °C with saturated steam for 30 minutes, cooled to ambient temperature and heated again. Each test cycle includes an integrity test with the FTC test (DOP test with paraffin), in accordance with EN 1822 and ASTM D 2986-91

STEAM-STERILISATION

Product requirement

The PU / PUR sterile filter elements withstand at least one hundred (100) in-line sterilisation cycles with purified, saturated steam:

In-line Sterilisation
142°C for 30 Min

Test method

Purpose: Sterilisation of the PU / PUR sterile filter element with saturated in-line steam.

Equipment

1. 1. PU / PUR test filter element
   2. stainless steel filter housing with pressure gauge
   3. sanitary valves
   4. steam generator
   5. Stainless steel steam filter, separation efficiency 1 micron (culinary steam)
   6. Saturated culinary steam (1 micron)

Methode

The PU / PUR sterile filter element is slowly heated in stages to 142 °C for 30 minutes, cooled to ambient temperature and heated again. The steam slowly enters the filter via a pressure regulator. The integrity of the filter element is tested with the FTC measurement after each sterilisation cycle in accordance with ASTM D 2986-91 and DIN EN 1822. The test results of the integrity test show that the sterile filter can withstand more than 100 sterilisation cycles when sterilised (steamed) in accordance with the specified conditions. The service life of the sterile filter elements is influenced by the process conditions, the use of oxidising additives, cleaning agents and other solvents. The service life therefore varies depending on the application.

The challenge of the INTEGRITY TEST for non-destructive aerosols

Product requirement

The PU / PUR sterile filter elements can be tested for integrity in EN1822 with the aerosol challange test for integrity.The testing device is liquid food grade white oil.
The minimum efficiency of the FTC is 99.99998% (retention rate).

Product requirement

Purpose: To determine the filter integrity using the aerosol challange test (with liquid food grade white oil).

Equipment

1. 1. test filter housing
   2. test filter element (6 pieces 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 VALA IRDATA challanges 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 chamber of the VALAIRDATA, where they are then detected with the aid of a laser particle counter.

Correlation to the aerosol bacteria challenge test

$$LRV = \frac{\text{Log10 Quantity of the Organism}}{\text{Number of organisms after filtration}}$$

CHEMICAL COMPATIBILITY

Product requirement

The materials of the PU / PUR Sterile Filter-Elements are Stainless Steel, Borosilicate Microfibre layer and Epoxy Resin as potting material. The Element is compatible with all natural gases and most toxic and aggressive media. The resistance decreases as the concentration of aggressive media increases.

Method

1. 1 Determine and log the following data for the filter element:
   - Integrity check
   - Dimensions
   - Flow rates
   - Outlet
   2. complete flow through the filter element with the test gas. Immerse the filter element in the test fluid.
   3. test procedure for 48 hours.
   4. determine and record the data listed in step 1.
   5. interpret the data:

R = stable
No change in performance, physical properties or dimensions has been observed.
LR = Limited resistance
Minor changes in the physical properties or dimensions of the filter element were observed, the filter integrity was not changed.
NR = Not resistant
The filter element was found to be unsuitable for the test medium.

Equipment

1. 1. PU / PUR test filter element
   2. pressure gauge
   3. thermocouple
   4. autoclave

Test method

Purpose: Determination of the resistance of filter elements to solvents, acids and bases.

The O-ring material was silicone.

Different O-ring materials can influence the chemical compatibility of the filter element.

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