CHALLIS
ANTIBACTERIAL

VALIDATION GUIDE - ASTM F838-05

Challis Ag+ Tap MicroFilter - Terminal disposable microfilter for Tap with incorporated anti-bacterial filter

Part I. Overview

1. Introduction

This report contains the validation data applicable to Challis Ag+ Tap microfilter with antibacterial filter. This microfilter works by external/internal filtration mode with an arrangement of hollow fiber in a ‘’U” shape. This microfilter is ready to provide bacteria-free water on tap usage point. It comes in a non-sterile packaging.

Challis Ag+ Tap MicroFilter was validated as follows:

- Measurement of flow microfilter to various water input pressures.
- Retention efficiency on Brevundimonas diminuta strain and on 9 challenges.

2. Presentation of the filtration system

The cut off chosen is 0.1 µ (micron), which is well below the minimum width of the smallest bacteria. This filtration, low cut-off, in no way alters the permeability of the microfilter as it is offset by a significant filter area installed therein.
This technologic choice is new on a market where one encounters rather flat membranes folded, lower filter areas, less compact, with good permeability but at the expense of a cutoff largest and often exceeds the limit of 0,22µm. This is only possible thanks to the particular geometry of the hollow fiber membranes.

The Challis Ag+ hollow fibers are made of polysulfone, which gives them very high properties in terms of mechanical resistance and thermal resistance. These fibers may be used on the hot water network, and can withstand tough use without impairing their performance.

Challis Ag+ Tap Microfilter

Technical data

Maximum use pressure	5 bar
Normal use pressure	2-4 bar
Peak Maximum temperature	70°C during 30 min maximum over the lifespan of the filter
Maximum use temperature	60°C
Overall length	103 mm

Properties

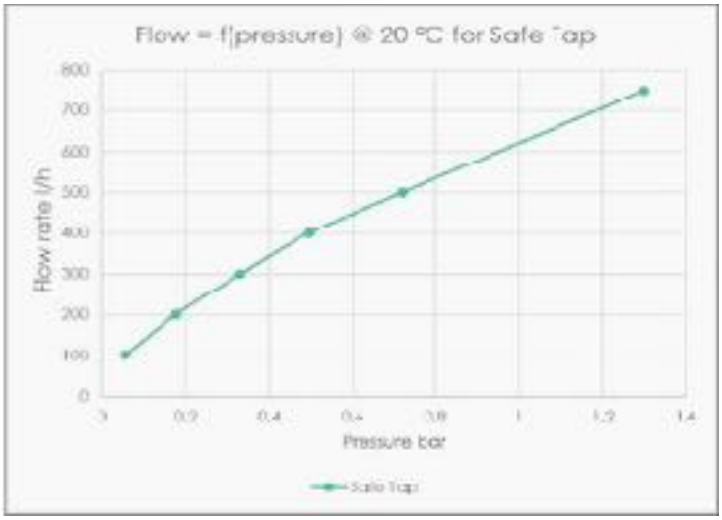
Filter medium	-	Hollow fibers
Type of Polymer	-	Polysulfone
Filtration Surface	cm ^{2}	**3600**

Part II. Validation of the hydraulic performances

The objective of this test was to establish typical water flow rates at various inlet water pressures. The Challis Ag+ Tap MicroFilter was subjected to different pressures and the filtration flow rates were measured. This test sample is installed on a water supply network fitted with a pre-filter cartridge UF. The purpose of this test is to demonstrate the Challis Ag+ Tap MicroFilter flow capacity used on a water exempted of turbidity (NTU).

Below, the water flow in L/min and curve L/h depending on the different pressures (bar)

Pressures/bar	0.0	0.1	0.3	0.4	0.7	1.3
Flow L/mn	1.7	3.3	5.0	6.6	8.3	12.



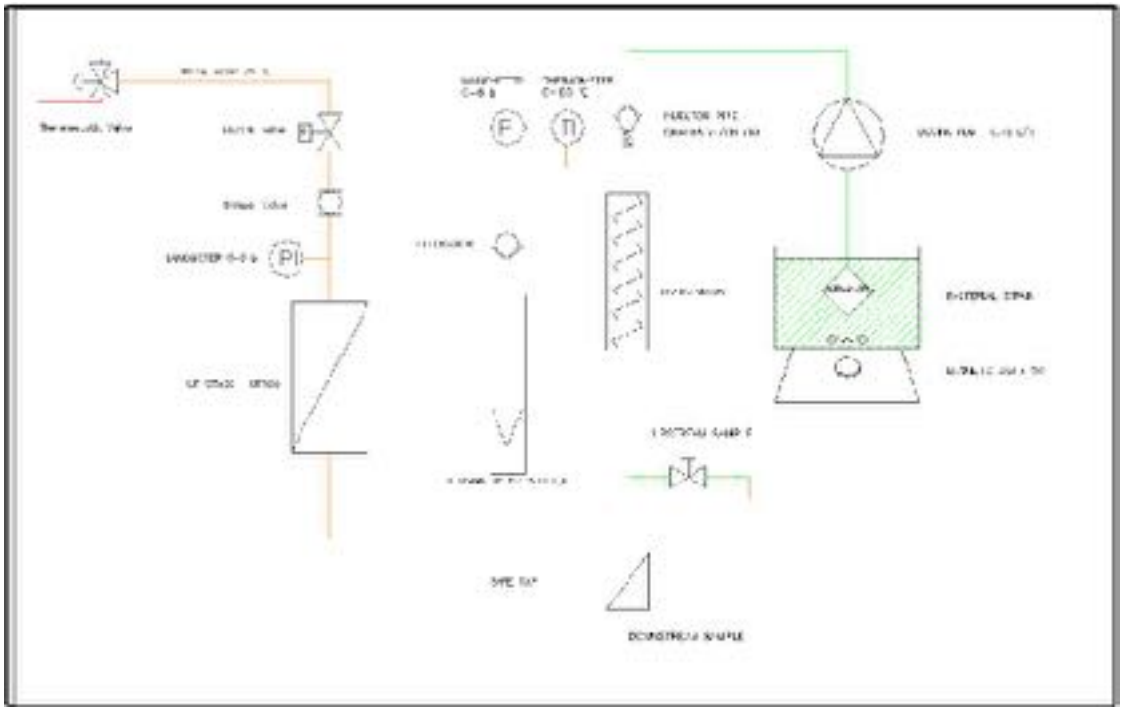
Part III. Retention test on strain *Brevundimonas-diminuta*

1. Objective

The test is performed by the laboratory FONDEREPHAR in Toulouse - FR. This testing laboratory is competent in the field of microbial engineering for the evaluation and enhancement of a product or industrial process.
The test performed made it possible to evaluate, under standard usage conditions, the bacterial retention capacity of the Challis Ag+ Tap MicroFilter, which is recommended for the tap point of use.
The test strain used is Brevundimonas diminuta CIP 103020 formerly known as Pseudomonas diminuta.

2.Test Conditions

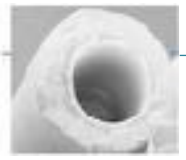
Test Strain	*Brevundimonas diminuta* CIP 103020
Growth and Maintenance Medium	Gélose TS (Biomérieux)
Incubation conditions:	37°C, under aerobiosis



Analysis period: 01/08/15 – 02/11/15

3.Methods

Throughout bacterial challenges, the tested filter is connected to the bench and performs two daily filtrations of 10 minutes each at a rate of 240 l / h. After the challenge J93, the microfilter will therefore filtered nearly 7,500 liters, in addition to the challenges, constituting in itself a dynamic aging of the cartridge.
The bacteria solution is prepared on-line by mixing tap water ultrafiltered with an UF100 cartridge, with a concentrated solution of the bacterial strain. This bacteria solution enters the Safetap microfilter whose the filtering surface is 3600 cm^2. The exterior from microfilter is disinfected.



Upstream of the microfilter, the system to inject the bacterial suspension is connected. A suspension of Brevundimonas-diminuta was prepared separately and titrated to a minimum of 10^9 bacteria /ml, in order to obtain during the injection, a minimal bacteria load of 3.1 10^6 bacteria/ml. The suspension reference sample is analysed.
The primary water tap is opened and the flow regulated to 240 l/h (4 l/min), the temperature of water is set at 25 °C. At the end of this step, the stop watch is started; this time point corresponds to time **T_0**. The injection of Brevundimonas diminuta into the water is started at T_0+ 1 min, the flow rate set at 0.75 l/h. All the filtered water (downstream) is collected in a tank to be analysed.
At T_0+4 min the injection is stopped and the thermostatic tap is turned off. In this way the amount of filtered bacteria is equal or greater than:
3.1 10^6 x 3 x 4 x 1000 = 3.75 10^{10} UFC, while we need 3600 x 10^7 = 3.6 10^{10} UFC.

- **A bacterial load greater than 10^7 CFU per cm^2 of filter surface, as required by the standard ASTM F838-05, is respected.**

4. Results

The following table indicates the results of the microbial counts for the 9challenges from D+1 to D+93. During the total duration of the challenge, the Challis Ag+ Tap MicroFilter operated at 240 l/h for ten minutes twice each day. At the end of 93 days it was filtered nearly 7500 liters of water. So, this challenge valid the bacterial retention of the microfilter on an effective period of 93 days (J93). It demonstrates also its mechanical strength under operating conditions.

				challenge 1 (J1)	challenge 2 (J2)	challenge 3 (J3)	challenge 4 (J4)	challenge 5 (J11)	challenge 6 (J32)	challenge 7 (J45)	challenge 8 (J63)	challenge 9 (J93)
A	Tc :(suspension filtrée)	UFC\ml	----	2,4 .10^9	2,2 .10^9	1,7 .10^9	2,6 .10^9	3,1 .10^9	3,2 .10^9	3,2 .10^9	3,2 10^9	3,2 .10^9
B	surface filtrante	cm^2	----	3600	3600	3600	3600	3600	3600	3600	3600	3600
C	volume injecté	ml	----	37,5	37,5	37,5	37,5	37,5	37,5	37,5	37,5	37,5
D	Challenge total	UFC	A x C	9 .10^{10}	8,25 .10^{10}	6,38 .10^{10}	9,75 .10^{10}	1,16 .10^{11}	1,2 .10^{11}	1,25 .10^{11}	1,88 10^{11}	9,00 .10^{10}
E	challenge total surface	UFC/cm^2	D / B	2,5 .10^7	2,29 .10^7	1,77 .10^7	2,71 .10^7	3,23 .10^7	3,33 .10^7	3,46 .10^7	5,23.10^7	2,50 .10^7
F	E : comptage aval cartouche B.diminuta	UFC	----	<1	<1	<1	<1	<1	<1	<1	<1	<1
G	Rétention	(log10)	log (E/F)	> 7,4	> 7,4	>7,2	> 7,4	>7,3	>7,5	>7,5	>7,7	>7,4

5. Conclusions

The results show, in the test conditions, a total retention of Brevundimonas diminuta strain for all samples analyzed on the 9 challenges made on the Challis Ag+ Tap MicroFilter and on a total period of 93 days.