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Report

**Determine adsorption potency of hollow-capillary filter devices
Art.-Code: QF10202HW, E.A.M Benelux B.V, NL-1336 GV ALMERE,
in due to consideration microbiological and chemical parameters (heavy metals
and organic contaminations). The procedure contains a maximal burden test and
a test under conditions of normal use.**

1. Introduction:

Adsorption potency of hollow-capillary filter devices Nr. QF10202HW of E.A.M Benelux is monitored in due to consideration microbiological and chemical parameters. Hollow-capillary filter devices can be used for general purposes in drinking water treatment, especially for filtration in terminal taps and fittings (e.g. hand showers). Drinking water ordinances are given in nearby all countries. Ordinances define limits for microbiological and chemical parameters. If these limits not exceed, water will used for every person without restrictions, throughout life. Under conditions of stagnation and secondary warming drinking water can be influenced negative. Normal microorganisms of drinking water multiply themselves so that increased colony forming units (CFU) define a risk of infection. Furthermore, heavy metals in alloys of tubes and fittings may be mobilized in drinking water. In view of some special chemical contaminations (e.g. estrogen derivates used in oral contraception), until now no limit is defined.

So, monitoring adsorption potency of the filter devices prior named in view of contaminations often found in drinking water is the key question in this report.

Two tests represent total testing procedure:

- Maximal burden - test
- Normal conditions of use -test

1.1 Maximal burden test:

Flushing filters devices with 100L of a suspension which contains the following parameters:

Legionella pneumophila	10 ⁵ CFU/mL	10 ¹⁰ CFU total
Cu	25 mg/L	2500 mg total
Mn	25 mg/L	2500 mg total
Fe	25 mg/L	2500 mg total
Cr	25 mg/L	2500 mg total
Hg	25 mg/L	2500 mg total
Cd	25 mg/L	2500 mg total
Ni	25 mg/L	2500 mg total
Pb	25 mg/L	2500 mg total
As	25 mg/L	2500 mg total
Zn	25 mg/L	2500 mg total

Microbiological count of Legionella pneumophila and concentration of heavy metals are determined in filtrate after flushing 50L and 100L volume. Furthermore, pressure difference between inlet and outlet side of the filter device is determined after 50 and 100L volume passed the filter.

Especially for Legionella pneumophila logarithmic reduction value (LRV) is calculated. For heavy metals decreasing concentration is expressed in percent.

1.2 Normal conditions of use – test:

Filter devices are flushed by a suspension which contains the following microbiological and chemical parameters:

1.2.1 Chemical parameters, inorganic

Chlorine	4,1 mg/L
Chlorine dioxide	1,5 mg/L
Aluminium	2,0 mg/L
Lead	0,5 mg/L
Iron	1,0 mg/L
Nitrite	1,0 mg/L
Nitrate	8,0 mg/L
Bromate	0,5 mg/L
Calcium	98,0 mg/L
Magnesium	72,0 mg/L
Fluoride	0,5 mg/L

1.2.2 Chemical parameters, organic

MCPA	0,6 µg/L
Mecoprop	0,5 µg/L
Benzene	3,0 µg/L
1,2-Dichlorethane	15,0 µg/L
Trichlorethen	25,0 µg/L
Bisphenol-A	50,0 ng/L
Estradiol	1,0 ng/L

1.2.3 Microbiological parameters:

Cryptosporidium spp., Oocysten	18 Oocysts / L (=200 Oocysts / 11L)
Giardia lamblia	18 Oocysts / L (=200 Oocysts / 11L)
Legionella pneumophila	810 CFU/100mL
Escherichia coli	50000 CFU/100mL

Total volume flush through one filter device is 6000L. After flushed a volume of 100L and final after 6000L, samples of filtrate are taking.

Hence, absorption potency of filter devices given in reduction potency (LRV, %) can be monitor by relevant parameters in levels of concentration which are possible in normal drinking water, well water or surface water under conditions of normal use. Furthermore, if a break of barrier occurs under conditions of normal use, this break will recognize.

2. Methods:

2.1 Manufacturing standard solutions – microbiological parameters:

Microbiological suspensions of *Legionella pneumophila* and *Escherichia coli* are diluted from defined microbiological reference material. Initial culture of strains is supplied via DSMZ (Deutsche Sammlung für Mikroorganismen und Zellkulturen, D-Braunschweig). Frozen dried reference material suspends in trypton-soya-bouillon, than sub-cultivating with three inoculation loops on tryptone-soya-agar to monitor pure cultures. If there are pure cultures, trypton-soya-bouillon for testing filter devices will be inoculate. Tryptone-soya-bouillon or –agar is the base of cultivating. For cultivate *Legionella pneumophila*, yeast extract, activated charcoal and GVPC inhibitor cocktail is added to trypton-soya-media.

Suspension of *E.coli* is ready to use after incubation time of 48 hours. For *Legionella pneumophila* suspension is decanted from activated charcoal sediment on the bottom of cultivating tank after 10 days (replicating time for this microorganism under optimal conditions is approx. 6 hours).

Cryptosporidium and *Giardia lamblia* (eucaryontic microorganisms) are get in cell culture by an institute of veterinary.

All bouillons cultivate until the final suspension after dilution to 100L or 6m³ has got approximately the count of microorganisms which is specified under section 1 (Introduction of this report).

2.2 Manufacturing standard solutions – chemical parameters:

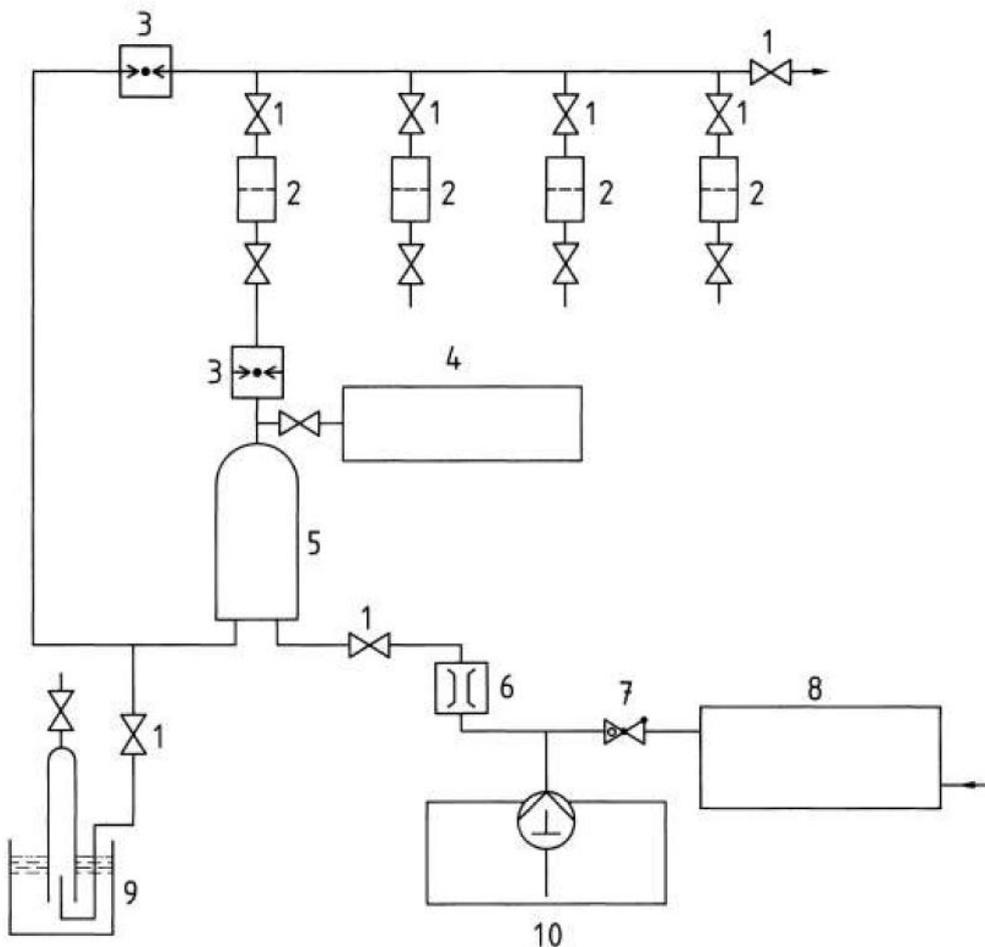
Inorganic-chemical parameters specified under section 1 are calibrated by salts of these parameters diluted stoichiometric in a defined volume of ultrapure water.

In view of organic parameters commercial ready to use standard solutions are used to get the final dilution specified under section 1.

2.3 Method of adsorption test:

Determination adsorption potency is in accordance to DIN 58356.

The following apparatus is used:



DIN 58356, Bild 1 - Prüfanordnung

Explanation:

- 1 Valve ($\frac{3}{4}$ ")
- 2 Control filter
- 3 Manometer
- 4 Controller
- 5 Housing for testing filter devices
- 6 Flowmeter
- 7 Regulator
- 8 Sterile filtration unit
- 9 Measurement of diffusion
- 10 Test suspension

Remarks: Control filter is not used in this test. The filtrate is collected in start, while and after the experiment when the defined total volume of test suspension flushed through the filter device. So it is possible to detect reduced adsorption potency over lifetime of filters. It is necessary to see that adsorption potential is equal over lifetime of filters. Furthermore, a break of filter is detectable, too.

Concentration of chemical and microbiological parameters is determined in initial test suspension. These parameters are determined after flushing 100L and 6m³ in filtrate. For chemical parameters, percent of reduction is calculated. For microbiological parameters logarithmic reduction value (LRV) is the calculated surrogate parameter.

3. Results:

Filter: Hollow-capillary device Art. Code: QF10202HW

3.1 Results of maximal burden test:

Parameter	conc _{initial}	conc _{after 50L}	% Red _{after50L}	conc _{after100L}	%Red _{after100L}
Legionella	3,8*10 ⁵ /mL	<1,0*10 ⁰ /mL	100%	<1,0*10 ⁰ /mL	100%
Cu	25,00 mg/L	0,18 mg/L	99,28 %	0,23 mg/L	99,08 %
Mn	25,00 mg/L	0,21 mg/L	99,16 %	0,26 mg/L	98,96 %
Fe	25,00 mg/L	0,15 mg/L	99,40 %	0,20 mg/L	99,20 %
Cr	25,00 mg/L	0,14 mg/L	99,44 %	0,23 mg/L	99,08 %
Hg	25,00 mg/L	0,11 mg/L	99,56 %	0,19 mg/L	99,24 %
Cd	25,00 mg/L	0,18 mg/L	99,28 %	0,22 mg/L	99,12 %
Ni	25,00 mg/L	0,34 mg/L	98,64 %	0,39 mg/L	98,44 %
Pb	25,00 mg/L	0,32 mg/L	98,72 %	0,42 mg/L	98,32 %
As	25,00 mg/L	0,19 mg/L	99,24 %	0,26 mg/L	98,96 %
Zn	25,00 mg/L	0,28 mg/L	98,88 %	0,41 mg/L	98,36 %

Remarks:

Legionella pneumophila was not found in filtrate after flushing 50L and 100L. After 100L bioburden is > 3,8*10¹⁰CFU/mL (= > 10 decimal powers or in another expression: > 10 one-log reduction). No break was observed under these conditions.

Burden of heavy metals was represented with 10 heavy metals, each by 25mg/L.

Before doing the test, the possibility of microbiological inhibition was calculated. An experiment showed that no inhibition was caused. No inhibition was found for E.coli over 48h incubating time, furthermore Legionella pneumophila was not inhibited over an incubating time of 10 days. So, testing adsorption potency for microbiological and chemical parameters (10 metals in form of their salts, each one by 25mg/L) can be done in one experiment.

3.2 Results of normal conditions of use - test:

3.2.1 Results of chemical parameters, inorganic:

Param.	Conc.-initial	conc.-100L	%	conc _{6000L}	%
Cl ₂	4,1 mg/L	0,005 mg/L	99,88 %	0,010 mg/L	99,76 %
ClO ₂	1,5 mg/L	0,004 mg/L	99,73 %	0,014 mg/L	99,07 %
Al	2,0 mg/L	0,012 mg/L	99,40 %	0,029 mg/L	98,55 %
Pb	0,5 mg/L	0,003 mg/L	99,40 %	0,011 mg/L	97,80 %
Fe	1,0 mg/L	0,005 mg/L	99,50 %	0,019 mg/L	98,10 %
NO ₂ ⁻	1,0 mg/L	0,009 mg/L	99,10 %	0,020 mg/L	98,00 %
NO ₃ ⁻	8,0 mg/L	0,008 mg/L	99,90 %	0,173 mg/L	97,84 %
BrO ₃ ⁻	0,5 mg/L	0,010 mg/L	98,00 %	0,014 mg/L	97,20 %
Ca	98,0 mg/L	57,000 mg/L	41,84 %	59,000 mg/L	39,80 %
Mg	72,0 mg/L	49,000 mg/L	31,94 %	53,000 mg/L	26,39 %
F ⁻	0,5 mg/L	0,029 mg/L	94,20 %	0,039 mg/L	92,20 %

3.2.2 Results of chemical parameters, organic:

Param.	Conc.-initial	conc.-100L	%	conc _{6000L}	%
MCPA	0,6 µg/L	0,010 µg/L	98,33 %	0,019 µg/L	96,83 %
Mecoprop	0,5 µg/L	0,065 µg/L	87,00 %	0,086 µg/L	82,80 %
Benzene	3,0 µg/L	0,007 µg/L	99,77 %	0,028 µg/L	99,07 %
Dichloreth	15,0 µg/L	0,180 µg/L	98,80 %	0,370 µg/L	97,53 %
Trichloreth	25,0 µg/L	0,010 µg/L	99,96 %	0,056 µg/L	99,78 %
Bisphen.A	50,0 ng/L	0,780 ng/L	98,44 %	1,340 ng/L	97,32 %
Estradiol	1,0 ng/L	0,290 ng/L	71,00 %	0,340 ng/L	66,00 %

3.2.3 Results of microbiological parameters:

	Initial:	after 6000L
Cryptosporidium spp.,	22 Oocysts / L	0 (< 1,3*10 ⁵ CFU)
Giardia lamblia	25 Oocysts / L	0 (< 1,5*10 ⁵ CFU)
Legionella pneumophila	890 CFU/100mL	0 (< 5,3*10 ⁷ CFU)
Escherichia coli	60000 CFU/100mL	0 (< 3,6*10 ⁹ CFU)

Equivalent to maximal burden test (3.1) in this test a break of filters was not observed.

Pressure levels:	Initial pressure	p = 4,0 bar
	Filtrate after 100L	p = 3,8 bar
	Filtrate afert 6000L	p = 2,9 bar

4. Discussion:

The maximal burden test shows that in the case of a maximal burden in form of microorganisms (*Legionella pneumophila*) and in form of 10 heavy metals no break occurs.

Legionella was reduced in full spectrum so filtrate can be called as sterile with an initial load of $3,8 \cdot 10^{10}$ CFU total.

The 10 heavy metals (Cu, Mn, Fe, Cr, Hg, Cd, Ni, Pb, As and Zn) were reduced > 98% with a load by 2500mg of each parameter (in form of a water soluble salt).

In this constellation tested filters represent sterile filtration. Concentration of heavy metals decreases over 2 decimal powers. Under the condition of a maximal burden, tested filters are secure.

Similar results were found in testing under normal conditions of use represented by flushing with 6000L moderate contaminated water (compare section 2.2).

- After a volume of 6000L no break of filter was observed for *Cryptosporidium* spp., *Giardia lamblia*, *Legionella pneumophila* and *Escherichia coli*.
- Adsorption potency for heavy metals was > 97%.
- Approx. 99% Chlorine and Chlorine dioxide was eliminated. Adsorption potency for Bromate is 98%..
- Inorganic salts (Nitrate, Nitrite) were reduced > 99%
- Concentration of Fluoride was reduced by 92%.
- Total hardness was reduced in filtrate by 40% for Calcium and 26% for Magnesium.
- Biocides and agricultural chemicals (e.g. pesticides) were adsorbed by > 82%. Halogenorganic substances (e.g. Dichloroethane) were reduced by > 97%.
- Substances with pharmacodynamic effects, like Estradiole, were reduced by > 66%.

Hence, in this constellation a sterile filtration was observed by all tested microorganisms. Agricultural chemicals, biocides, oxidative disinfectants, fluoride and substances with pharmacodynamic effects were reduced by treatment of water with tested filter devices in an appropriate level. In this constellation filters are reliable and secure.

In total, tested filter devices indicate an appropriate adsorption potency for bacterial and eucaryotic microorganisms. Tested filter devices are qualified to reduce the risk of drinking water associated infections and intoxications by a volume of 6000L moderate contaminated water.

Service life is to determine by perfused volume (in Liters). It is not a function over days. A grow through filter matrix was not detected.

Expiry date after installation has to be calculated by perfused volume. Decreased perfusion pressure indicates that service time occurs.

A negative influence on drinking water was not observed.

Under consideration of appropriate results and the fact that tested filter devices causes no hazards, the filters tested module a positive opinion for use as pure drinking water, as well as from the medical devices sector, for CE declaration (in accordance to 93/42/CEE) can be stated. CE declaration has to be done with a notified body. Using for treatment of drinking water is possible in accordance to local law and regulations.

For further questions, contact the author via phone 0049-175-9150334 or e-mail: ullischmelz@aol.com

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Ulrich Schmelz', written in a cursive style.

Ulrich Schmelz, M.D.

Additional report to the report from April 11th, 2014:

Examination the microbiological barrier of hollow-capillary filters WS10002HW under conditions of microbiological activity

Introduction:

A well known phenomena in filter technologies is microbiological growth through the filter barrier.

Under conditions of microbiological activity, examination of microbiological growth through filter barrier has been evaluated.

Methods:

Each of three filters type WS10002HW was flushed with 10 l Tryptone-Soya-Bouillon. The Bouillon was doted with 10^3 /mL CFU Escherichia coli and Legionella pneumophila. After flushing, every filter was loaded with 10^7 CFU total bioburden.

The bouillon represents organic C and N sources, so microbiologic activity is possible. To enforce microbiologic activity, filters were placed in an incubator for 7 days by 36°C.

After this, filters were flushed with 1 l peptone water. The filtrate in this process was examined by Escherichia coli and Legionella pneumophila.

Furthermore, the filters were flushed reverse by 2 l peptone water. The reverse flushed fluid was sampled and examined by Escherichia coli and Legionella pneumophila.

Results:

Initial CFU:

Escherichia coli:	$2,8 * 10^3$ KbE/mL
Legionella pneumophila:	$6,3 * 10^3$ KbE/mL

Filtrate – CFU after incubation time of 7 days:

Escherichia coli: < 1,0 * 10⁰ KbE/mL
Legionella pneumophila: < 1,0 * 10⁰ KbE/mL

Reverse flushed fluid – CFU after incubation time of 7 days:

Escherichia coli: 5,1 * 10⁶ KbE/mL
Legionella pneumophila: 2,3 * 10⁵ KbE/mL

Conclusion

After 7 days incubation time (36°C) with an initial load of 10⁷ CFU, no growing through (clamping) the barrier of examined filters was observed under conditions of microbiological activity (which was represented by a substrate formed by Tryptone-Soya-Bouillon in filters after initial load).

Under testing conditions, germ number (CFU) is increasing over the time. That phenomena show, that microbiological activity is real given.

The maximal influence of microbiological activity was represented in this test.

Testing conditions were not able to break the microbiological barrier of tested filters.

For further questions, contact the author via phone 0049-175-9150334 or e-mail: ullischmelz@aol.com

Sincerely yours,



Ulrich Schmelz, M.D.