PALL Medical

Validation Guide

160330.2WUS

Pall QPoint™ Shower Water Filter Assembly

QPoint - More than Filtration

Contents

Part 1 Overview

1. Introduction

This guide contains data applicable to the Pall QPoint Shower Water Filter Assembly. The QPoint Shower Water Filter Assembly consists of two components, a non-sterile reusable Docking Station and a sterile disposable Filter Capsule with a rose outlet.

Table 1. Pall QPoint variant identification

Component	Description	Product code
QPoint Docking Station	Shower assembly with 1/2 inch threaded inlet	QDS
QPoint Filter Capsule	0.2 µm, rose outlet, 12 per case	QR212U
	0.2 µm, rose outlet, 2 per case	QR22U

N.B. Throughout this guide, reference to Pall QPoint Docking Station – Shower Assembly refers to product code QDS and Pall QPoint Filter Capsule refers to QR212U or QR22U unless otherwise stated.

1.1 Filter Capsule

Pall QPoint Filter Capsules are supplied sterile, ready for use. Following manufacture, sterilization is achieved by gamma irradiation. The conditions used ensure a minimum Sterility Assurance Level of 10^{-6}. The sterilization process has been validated and is routinely controlled in compliance with the following standards:

- ISO 11137-1:2006 + A1: 2013, ISO 11137-2: 2013, ISO 11137-3: 2006 'Sterilization of Healthcare Products – Radiation - Part 1 - Requirements for development, validation and routine control of a sterilization process for medical devices. Part 2 - Establishing the sterilization dose. Part 3 - Guidance on dosimetric aspects'.

Please contact Pall if further information about the gamma sterilization process is required.

Pall QPoint Filter Capsules are validated by:

- Liquid microbial challenge tests using *Brevundimonas diminuta* (ATCC 19146) using the industry standard method for 0.2 µm sterilizing grade filters, ASTM F838-05[1], and in simulated intermittent use
- Liquid microbial challenge tests using *Legionella pneumophila* sero-group 1 (NCTC12821), *Pseudomonas aeruginosa* (ATCC 25668), *Escherichia coli* (ATCC 11775), *Mycobacterium gordonae* (NCTC 10267), and *Cryptosporidium parvum* (ATCC 9027) using a method modified from the industry standard method for 0.2 µm sterilizing grade filters[1]
- Liquid microbial challenge tests using *Legionella pneumophila* sero-group 1 (NCTC 11192) and *Aspergillus fumigatus* (NCPF 2140) in combination in simulated intermittent use
- Evaluation of bacteriostatic additive according to ISO 22196[2]
- Typical flow rate measurements at various inlet water pressures
- Maximum operating temperature and pressure rating measurements
- Compliance with the British Standard for Testing for Non-metallic Materials for use with Drinking Water (BS 6920)[3] and European Regulation (EC) number 1935/2004[4] relating to materials and articles intended to come into contact with food
- Biocompatibility compliance with ISO 10993[5]
- Evaluation of shelf life

Please contact Pall if more detailed information on the test methods is required.

1.2 Docking Station – Shower Assembly

Pall QPoint Docking Stations are supplied non-sterile and are:

- Compliant with Filter Capsule maximum operating temperature and pressure rating measurements
- Compliant with the British Standard for Testing for Non-metallic Materials for use with Drinking Water (BS 6920)[3] and European Regulation (EC) number 1935/2004[4] relating to materials and articles intended to come into contact with food

Please contact Pall if more detailed information on the test methods is required.

2. Summary of conclusions

2.1 Verification of 0.2 µm sterilizing grade filter performance

Pall QPoint Filter Capsules retain *Brevundimonas diminuta* when tested by industry standard laboratory liquid microbial challenge tests used for validating 0.2 µm sterilizing grade filters to $\geq 10^7$ colony forming units (CFU)/cm^2 of effective filtration area.[1]

2.2 Verification of retention of various waterborne microorganisms

Pall QPoint Filter Capsules retain *Legionella pneumophila* sero-group 1, P*seudomonas aeruginosa, Escherichia coli,* and *Mycobacterium gordonae* when tested by modified industry standard laboratory liquid microbial challenge tests used for validating 0.2 µm sterilizing grade filters to $\geq 10^7$ CFU/cm^2 of effective filtration area. *Cryptosporidium parvum* was also retained in laboratory liquid challenge tests at a level of $\geq 10^3$ CFU/cm^2 of effective filtration area.

2.3 Microbial retention in intermittent use

Pall QPoint Filter Capsules retain *Brevundimonas diminuta*, following simulated intermittent use (mimicking on/off water flow) for two calendar months (maximum of 62 days), to $\geq 10^7$ CFU/cm^2.

Pall QPoint Filter Capsules also retain L*egionella pneumophila* (to $\geq 10^7$ CFU/cm^2) and *Aspergillus fumigatus* (to $\geq 10^3$ CFU/cm^2) following simulated intermittent use for two calendar months (maximum of 62 days).

2.4 Evaluation of bacteriostatic additive

Pall QPoint Filter Capsules contain a bacteriostatic additive incorporated within the plastic to reduce external microbial contamination.

A reduction of > 99 % *Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus* or *Staphylococcus epidermidis* was observed after 24 hours contact when tested under laboratory conditions according to a method based on ISO 22196[2]. The bacteriostatic additive maintained effectiveness over the lifetime of the product.

2.5 Typical flow rates at nominal water pressures

Pall QPoint Filter Capsules typically deliver flow rates at inlet water pressures as detailed in Table 2:

Table 2. Mean typical water flow rates at 68 °F (20 °C)

Flow rate	Water pressure, psi (approx. bar)				
	15 (1)	30 (2)	45 (3)	60 (4)	75 (5)
gal/min	1.5	2.6	3.5	4.2	5.0
L/min	5.7	9.9	13.1	16.0	18.8

2.6 Maximum operating temperature and pressure

Pall QPoint Filter Capsules with Pall QPoint Docking Stations – Shower Assemblies have been qualified to operate continually at up to 140 °F (60 °C) and 75 psi (5 bar) inlet pressure for 62 days.

2.7 Temperature tolerance during thermal sanitisation

Pall QPoint Filter Capsules with Pall QPoint Docking Stations – Shower Assemblies will withstand exposure to water at 167 °F (75 °C) for a total cumulative period of 90 minutes over the life of the Filter Capsule, as typically used in water systems to control the growth of microorganisms and/or in the case of critical contamination.

2.8 BS 6920 and 1935/2004 compliance

Fluid pathway polymeric materials relating to Pall QPoint Filter Capsules and Pall QPoint Docking Stations – Shower Assembly meet BS 6920[3] and European Regulation (EC) number 1935/2004[4].

2.9 ISO 10993 biocompatibility compliance

Pall QPoint Filter Capsules meet the relevant requirements of ISO 10993.

2.10 Shelf life

Pall QPoint Filter Capsules within intact unit packaging can be used for up to 5 years post sterilization.

Part II Microbial validation

1. Microbial challenge testing for verification of 0.2 µm sterilizing grade filter performance

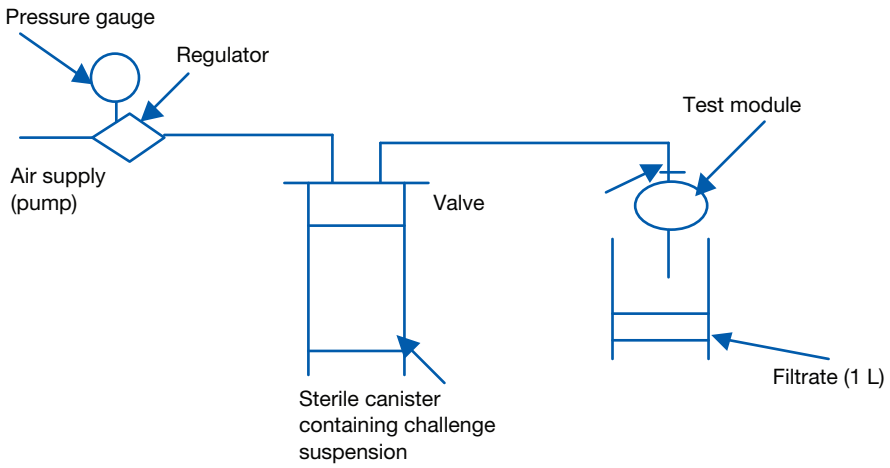
1.1 Introduction

The aim of this test was to confirm that the Pall QPoint Filter Capsule completely retains the standard test organism *Brevundimonas diminuta* (ATCC 19146) when tested according to the industry standard method defined for validating 0.2 µm sterilizing grade filters.[1] For sterilizing grade performance, complete retention of a challenge greater or equal to 1×10^7 CFU/cm^2 effective filtration area must be demonstrated.

1.2 Summary of methods

The method follows the principles of ASTM F838-05[1] and Health Industry Manufacturers Association (HIMA) guidance[6] for validating 0.2 µm sterilizing grade filters. A number of Filter Capsules with the same materials and processes of construction and with the same sterilizing grade media as QR212U and QR22U were each subjected to a liquid microbial challenge test using the apparatus indicated in Figure 1.

Figure 1. Microbial challenge test rig for verification of sterilizing grade filter performance



The sterile pressure vessel was filled with 0.2 µm filtered sterile deionised water. A single bolus inoculum of *Brevundimonas diminuta* (ATCC 19146) was added to the vessel and mixed thoroughly to give a challenge level of greater than or equal to 1 x 10^7 CFU/cm^2 effective filtration area. This was sampled aseptically to confirm the challenge level. 0.26 gal (1 L) challenge solution was passed through the filter under test at 15 psi (1 bar) pressure and the collected filtrate passed through 0.2 µm analysis membrane filter discs. The analysis membranes were incubated on Tryptone Soya Agar (TSA) at 86 °F (30 °C) for at least 48 hours and examined for microbial growth.

1.3 Results

A summary of results is shown in Table 3. All analysis membranes were found to be free of *B. diminuta*.

Table 3. Retention of *B. diminuta* liquid challenge by Pall QPoint Filter Capsules

Component	Total *B. diminuta* challenge CFU	Total *B. diminuta* challenge CFU/cm^2 effective filtration area	Recovery
J071007435151	2.08 x 10^{10}	3.22 x10^7	0
J071005535151	2.08 x 10^{10}	3.22 x10^7	0
J072001435151	2.08 x 10^{10}	3.22 x10^7	0
J072000735151	2.08 x 10^{10}	3.22 x10^7	0

1.4 Conclusions

Pall QPoint Filter Capsules are capable of completely retaining *B. diminuta* in microbial challenge tests defining 0.2 µm sterilizing grade filters, at a level of ≥ 10^7 CFU/cm^2 effective filtration area.

2. Verification of retention of various waterborne microorganisms

2.1 Introduction

The aim of this series of tests was to confirm that the Pall QPoint Filter Capsule retains various relevant waterborne microorganisms. Retention of *Legionella pneumophila* (NCTC12821), *Pseudomonas aeruginosa* (ATCC 25668), *Escherichia coli* (ATCC 11775), *Mycobacterium gordonae* (NCTC 10267), and *Cryptosporidium parvum* (ATCC 9027) using a modified industry standard method was investigated.

2.2 Summary of methods

2.2.1 Retention of *L. pneumophila, P. aeruginosa* or *E. coli*

A number of Filter Capsules with the same materials and processes of construction and with the same sterilizing grade media as QR212U and QR22U were each subjected to a liquid *L. pneumophila, P. aeruginosa* or *E. coli* challenge test using the apparatus indicated in Figure 1. The analysis membranes from *P. aeruginosa* and *E. coli* challenge tests were incubated on TSA at 99 °F (37 °C) for at least 48 hours and examined for microbial growth. The analysis membranes from *L. pneumophila* challenge tests were incubated on GVPC agar at 97 ° F (36 °C) for 10 days and examined for microbial growth.

2.2.2 Retention of *M. gordonae*

A number of Filter Capsules with the same materials and processes of construction and with the same sterilizing grade media as QR212U and QR22U were each subjected to a liquid *M. gordonae* challenge test using apparatus similar to that indicated in Figure 1 with the exception that the 0.26 gal (1 L) challenge solution was pumped through the test filter at 0.13 gal/min (500 mL/min) and the filtrate collected. 0.03 gal (100 mL) collected effluent was passed through 0.45 µm analysis membrane discs. The analysis membranes were incubated on *Mycobacterium* selective BBL Sven H11 Agar supplemented with Middlebrook OADC Enrichment and incubated at 95 °F (35 °C) for 28 days.

2.2.3 Retention of *C. parvum*

A number of Filter Capsules with the same materials and processes of construction and with the same sterilizing grade media as QR212U and QR22U were each subjected to a liquid *C. parvum* challenge test using apparatus similar to that indicated in Figure 1 with the exception that the 0.26 gal (1 L) challenge solution was pumped through the test filter at 0.13 gal/min (500 mL/min) and the filtrate collected. 0.02 gal (50 mL) collected effluent was analyzed for the presence of *C. parvum*.

2.3 Results

Table 4. Retention of *L. pneumophila* liquid challenge by Pall QPoint Filter Capsules

Filter ref	Filter serial number	Total *L. pneumophila* challenge CFU	Total *L. pneumophila* challenge CFU/cm^2 effective filtration area	Recovery
J3515AE	435	8.3×10^{10}	12.7×10^{7}	0
J3515AE	320	8.3×10^{10}	12.7×10^{7}	0
J3515AE	302	8.3×10^{10}	12.7×10^{7}	0
J3515AE	440	8.3×10^{10}	12.7×10^{7}	0
J3515AE	317	8.3×10^{10}	12.7×10^{7}	0
J3515AF	295	8.3×10^{10}	12.7×10^{7}	0
J3515AF	285	8.3×10^{10}	12.7×10^{7}	0
J3515AF	467	8.3×10^{10}	12.7×10^{7}	0
J3515AF	465	8.3×10^{10}	12.7×10^{7}	0
J3515AF	453	8.3×10^{10}	12.7×10^{7}	0

Table 5. Retention of *P. aeruginosa* liquid challenge by Pall QPoint Filter Capsules

Filter ref	Filter serial number	Total *P. aeruginosa* challenge CFU	Total *P. aeruginosa* challenge CFU/cm² effective filtration area	Recovery
J3515C	003	1.40×10^{10}	1.75×10^{7}	0
J3515A	013	1.40×10^{10}	1.75×10^{7}	0
J35315A	023	1.40×10^{10}	1.75×10^{7}	0

Table 6. Retention of *E. coli* liquid challenge by Pall QPoint Filter Capsules

Filter ref	Filter serial number	Total *E. coli* challenge CFU	Total *E. coli* challenge CFU/cm² effective filtration area	Recovery
J3515A	001	1.38×10^{10}	1.73×10^{7}	0
J3515A	008	1.38×10^{10}	1.73×10^{7}	0
J3515A	017	1.38×10^{10}	1.73×10^{7}	0

Table 7. Retention of *M. gordonae* liquid challenge by Pall QPoint Filter Capsules

Filter ref	Total *M. gordonae* challenge CFU	Total *M. gordonae* challenge CFU/cm² effective filtration area	Recovery
J3515C-1	3.70×10^{10}	4.63×10^{7}	0
J3515C-2	3.70×10^{10}	4.63×10^{7}	0
J3515C-3	3.70×10^{10}	4.63×10^{7}	0

Table 8. Retention of *C. parvum* liquid challenge by Pall QPoint Filter Capsules

Filter ref	Total *C. parvum* challenge CFU	Total *C. parvum* challenge CFU/cm² effective filtration area	Recovery
1	1.5×10^{6}	2.3×10^{3}	0
2	1.5×10^{6}	2.3×10^{3}	0
3	1.5×10^{6}	2.3×10^{3}	0

2.4 Conclusions

Pall QPoint Filter Capsules retain *Legionella pneumophila, Escherichia coli, Pseudomonas aeruginosa* and *Mycobacterium gordonae* in laboratory liquid challenge tests at a level of $\geq 10^{7}$ CFU/cm² of effective filtration area. *Cryptosporidium parvum* was also retained in laboratory liquid challenge tests at a level of $\geq 10^{3}$ CFU/cm² of effective filtration area.

3. Microbial retention in intermittent use (regular on-off flow)

3.1 Introduction

The aim of this series of tests was to confirm that Pall QPoint Filter Capsules retain *B. diminuta* (used as the challenge organism for the 0.2 µm sterilizing grade filter validation) and selected clinically relevant microorganisms such as *L. pneumophila* and *A. fumigatus* following simulated intermittent use for a period of two calendar months (maximum 62 days). The intermittent use scenario mimics the regular switching on and off of water points-of-use, and potential fatigue, which may be experienced in the real-life user setting.

3.2 Summary of methods

This method follows the principles of ASTM F838-05[1] guidance for validating 0.2 µm sterilizing grade membranes. The sterile test apparatus was assembled as shown in Figure 2.

Pall QPoint Filter Capsules with the same materials and processes of construction and with the same sterilizing grade media as QR212U and QR22U were tested under intermittent water flow. The pump was set to deliver a flow of approximately 2.4 gal/min (9 L/min) operating for 30 minutes per hour for 7 hours per day, during the working day.

Prior to microbial challenge a 0.03 gal (100 mL) water sample was taken downstream of the test filter into a sterile container. A calculated volume of the *B. diminuta* challenge suspension was added via the inoculation port and a 0.03 gal (100 mL) sample was taken immediately downstream of the test filter. The 0.03 gal (100 mL) water samples were filtered through 0.2 µm analysis membranes, which were placed onto Tryptone Soya Agar (TSA). A viable cell count was performed on the challenge suspension. All plates were incubated for up to 48 hours at 86 °F (30 °C).

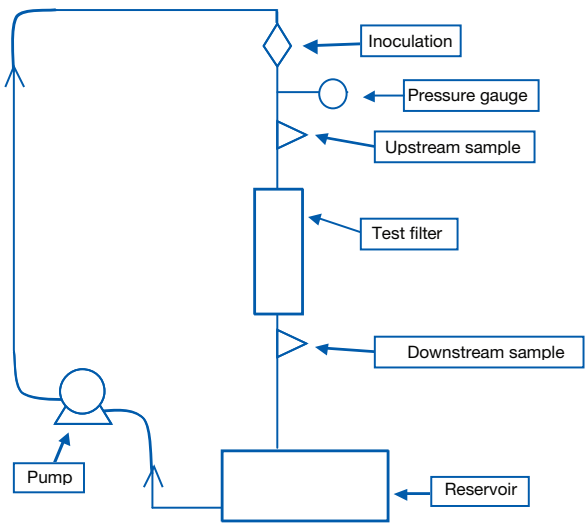
Microbial challenge and sample collection and analysis were performed as above, on day 0, 35, 68, 90 and 96 to complete the assessment. Results are shown in Table 9.

Similarly, two Pall QPoint Filter Capsules with the same materials and processes of construction and with the same sterilizing grade media as QR212U and QR22U (J3515A) were tested using a *Legionella pneumophila* (NCTC 11192) and *Aspergillus fumigatus* (NCPF 2140) challenge. In this test, a calculated volume of *Legionella pneumophila* (NCTC 11192) and *Aspergillus fumigatus* (NCPF 2140) challenge suspension was added via the inoculation port and a 0.13 gal (500 mL) and 0.06 gal (200 mL) sample was taken immediately downstream of the test filter. The 0.13 gal (500 mL) water samples were filtered through 0.45 µm analysis membranes, which were placed onto Petri dishes of Sabouraud Dextrose selective medium. A viable cell count was performed on the challenge suspension. All plates were incubated for 10 days at 108 °F (42 °C). The 0.06 gal (200 mL) water samples were filtered through 0.45 µm analysis membranes, which were placed onto *legionella* selective medium GVPC. A viable cell count was performed on the challenge suspension. All plates were incubated for 72 hours at 95 °F (35 °C).

Microbial challenge and sample collection were performed as above, at days 36, 64 and at the beginning of day 93 to complete the assessment. Results are shown in Table 10.

Both challenge tests were run significantly beyond the 62 day life of the Filter Capsule to represent worse case with respect to water throughput and potential fatigue in the real-life user setting and the intermittent switching on and off of the water supply.

Figure 2. Microbial challenge test apparatus for simulated intermittent use



3.3 Results

A summary of results are shown in Tables 9 and 10. All samples of water collected from the test filters were found to be free of the test organism.

Table 9. Retention of *B. diminuta* liquid challenge by Pall QPoint Filter Capsules during intermittent use

Filter ref	Challenge day	Total challenge (CFU/cm^2) effective filtration area	*B. diminuta* Recovery	
			Pre challenge recovery CFU	Post challenge recovery CFU
J3515A-001	0	2.93×10^6	0	0
	35	4.68×10^6	0	0
	68	4.86×10^5	0	0
	90	2.20×10^5	0	0
	96	2.75×10^7	0	0
	Total	**3.58×10^7**	**0**	**0**
J3515A-004	0	2.93×10^6	0	0
	35	4.68×10^6	0	0
	68	4.86×10^5	0	0
	90	2.20×10^5	0	0
	96	2.75×10^7	0	0
	Total	**3.58×10^7**	**0**	**0**

Table 10. Retention of *L. pneumophila* and *A. fumigatus* liquid challenge by Pall QPoint Filter Capsules during intermittent use

Filter ref	Challenge day	*L. pneumophila*			*A. fumigatus*		
		Total challenge (CFU/cm^2) effective filtration area	Pre challenge recovery CFU	Post challenge recovery CFU	Total challenge (CFU/cm^2) effective filtration area	Pre challenge recovery CFU	Post challenge recovery CFU
J3515A-1	0	5.4×10^5	0	0	1.4×10^3	0	0
	36	7.0×10^5	0	0	7.0×10^2	0	0
	64	7.8×10^5	0	0	6.0×10^2	0	0
	99	1.0×10^7	0	0	1.8×10^3	0	0
	Total	**1.2×10^7**	**0**	**0**	**4.5×10^3**	**0**	**0**
J3515A-2	0	5.4×10^5	0	0	1.4×10^3	0	0
	36	7.0×10^5	0	0	7.0×10^2	0	0
	64	7.8×10^5	0	0	6.0×10^2	0	0
	99	1.0×10^7	0	0	1.8×10^3	0	0
	Total	**1.2×10^7**	**0**	**0**	**4.5×10^3**	**0**	**0**

3.4 Conclusions

Pall QPoint Filter Capsules are capable of retaining ≥ 1×10^7 CFU/cm^2 *Brevundimonas diminuta* or ≥ 1×10^7 CFU/cm^2 *Legionella pneumophila* and ≥ 10^3 CFU/cm^2 *A. fumigatus* over the 62 day life of the filter during simulated intermittent use.

4. Bacteriostatic additive

4.1 Introduction

The series of tests assessed the efficacy of the non-leaching silver based bacteriostatic additive incorporated within the plastic housing of the Pall QPoint Filter Capsule. These tests, based on ISO 22196[2], were performed independently by an external laboratory.

4.2 Summary of methods

Artificially aged samples of the plastic materials incorporating the bacteriostatic additive used for the housings Pall QPoint Filter Capsules were inoculated with *E. coli*, *Staphylococcus aureus, Staphylococcus epidermidis* or *P. aeruginosa* on day 0, 31 and 62. The number of viable cells on the surface of the samples after 24 hours contact was determined. Control samples of the plastic housing materials without the bacteriostatic additive incorporated were evaluated in the same way. These tests determined both the efficacy of the bacteriostatic additive and whether that efficacy is maintained over the lifetime of the Filter Capsule.

4.3 Results

A summary of the results is shown in Tables 11 and 12 for the polypropylene and polyester housing materials used in the QPoint Filter Capsules incorporating the bacteriostatic additive.

Table 11. Evaluation of bacteriostatic additive incorporated in polypropylene

	Day 0			Day 31			Day 62		
	CFU/cm²			CFU/cm²			CFU/cm²		
Test organism	Control	Test	% reduction	Control	Test	% reduction	Control	Test	% reduction
E. coli	5.4×10^5	<11.11	≥99.99	3.0×10^5	<11.11	≥99.99	3.9×10^5	<11.11	≥99.99
P. aeruginosa	2.9×10^5	<11.11	≥99.99	2.5×10^5	<11.11	≥99.99	2.1×10^4	5.6×10^1	99.73
S. epidermidis	4.3×10^3	<11.11	≥99.74	2.0×10^3	<11.11	≥99.44	3.3×10^3	<11.11	≥99.66
S. aureus	3.8×10^3	<11.11	≥99.71	9.2×10^3	<11.11	≥99.88	2.5×10^4	<11.11	≥99.96

Table 12. Evaluation of bacteriostatic additive incorporated in polyester

	Day 0			Day 31			Day 62		
	CFU/cm²			CFU/cm²			CFU/cm²		
Test organism	Control	Test	% reduction	Control	Test	% reduction	Control	Test	% reduction
E. coli	2.2×10^5	<11.11	≥99.99	1.3×10^4	<11.11	≥99.92	2.9×10^5	<11.11	≥99.99
P. aeruginosa	8.6×10^4	<11.11	≥99.99	1.9×10^4	<11.11	≥99.94	2.3×10^4	<11.11	≥99.95
S. epidermidis	1.0×10^4	<11.11	≥99.91	1.1×10^4	<11.11	≥99.89	3.4×10^3	<11.11	≥99.67
S. aureus	1.0×10^4	1.3×10^1	99.87	3.6×10^3	<11.11	≥99.69	1.4×10^3	1.2×10^1	≥99.14

4.4 Conclusions

The non-leaching, silver based bacteriostatic additive incorporated within the Pall QPoint Filter Capsule housing plastics is capable of inhibiting growth of externally introduced microbial contamination by > 99% within 24 hours. Its effectiveness is maintained over a 2 month period.

Part III Validation of physical characteristics

1. Typical flow rate at various inlet pressures

1.1 Introduction

The aim of this test was to illustrate typical water flow rates that might be expected using the Pall QPoint Shower Water Filter Assembly at different inlet water pressures.

1.2 Summary of methods

A number of Pall QPoint Filters Capsules sterilized by gamma irradiation, were subjected to water flow pressure drop testing. Filter capsules were installed in a test rig consisting of a recirculation loop containing filtered deionized water.

After a short period of recirculation to allow the system to stabilize readings were taken of flow rates at different pressure levels (15 psi or 1 bar increments); water temperature was approsimately 68 °F (20 °C).

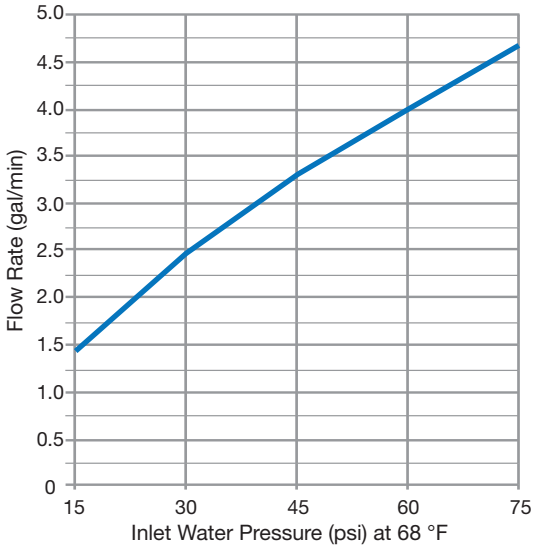
1.3 Results

A summary of results is shown in Table 13 and represented graphically in Figure 3.

Table 13. Typical clean water flow rates at various inlet water pressures, psi (approx. bar), water temperature 68 °F (20 °C)

	Water flow gal/min (L/min) at the following inlet pressures, psi (approx. bar)				
Filter	15 (1)	30 (2)	45 (3)	60 (4)	75 (5)
1	1.5 (5.7)	2.5 (9.4)	3.2 (12.3)	4.0 (15.3)	4.8 (18.0)
2	1.5 (5.6)	2.4 (9.1)	3.2 (12.3)	4.0 (15.0)	4.5 (17.0)
3	1.5 (5.8)	2.5 (9.5)	3.3 (12.6)	4.1 (15.6)	4.9 (18.5)
4	1.4 (5.4)	2.8 (10.6)	3.5 (13.4)	4.3 (16.4)	5.2 (19.5)
5	1.4 (5.3)	2.8 (10.5)	3.7 (14.0)	4.5 (16.9)	5.3 (20.0)
6	1.7 (6.6)	2.7 (10.3)	3.7 (13.9)	4.4 (16.8)	5.3 (20.0)
Mean	1.5 (5.7)	2.6 (9.9)	3.5 (13.1)	4.2 (16.0)	5.0 (18.8)

Figure 3. Graphical representation of clean water flow rates at various inlet water pressures, at 68 °F (20 °C) water temperature



1.4 Conclusions

At 15 – 75 psi (1 – 5 bar) water pressure, Pall QPoint Filter Capsules typically deliver flow rates of 1.5 to 5.0 gal/min (5.7 to 18.8 L/min).

Note: Water flow rates during use will be dependent on the particulate contamination levels of the influent water supply. In heavily contaminated water systems, flow rates will drop as the filters retain contaminants and they eventually may become blocked.

Pall can recommend suitable prefiltration for heavily contaminated influent water qualities or under other operating conditions.

2. Maximum operating temperature and pressure rating

2.1 Introduction

The aim of this series of tests was to confirm that Pall QPoint Filter Capsules with QPoint Docking Station - Shower Assembly are capable of operating at a continuous maximum temperature of 140 °F (60 °C) combined with a maximum inlet pressure of 75 psi (5 bar) and also able to withstand 167 °F (75 °C) for a total cumulative period of 1.5 hours (90 minutes) over the 62 day life of the Filter Capsule.

2.2 Summary of methods

Two sterile Pall QPoint Filter Capsules were connected by QPoint Docking Station – Shower Assembly and placed into a purpose built rig designed to recirculate hot water under high pressure in defined cycles. The filters were subjected to 1000 x 5 minute cycles of water at 104 °F (40 °C), 1150 x 5 minute cycles of water at 140 °F (60 °C) and 18 x 5 minute cycles of water at 167 °F (75 °C). Each test cycle was set at an inlet pressure of 75 psi (5 bar). Each Filter Capsule was integrity tested after cycling at each temperature. The integrity test is directly correlated with bacterial removal efficiency.

2.3 Results

A summary of results is shown in Table 14. Filters tested retained their integrity after 1000 x 5 minute 104 °F (40 °C) water cycles, 1150 x 5 minute 140 °F (60 °C) water cycles and 18 x 5 minute 167 °F (75 °C) water cycles at 75 psi (5 bar) inlet pressure.

Table 13. Maximum operating temperature and pressure rating: forward flow integrity test results

Filter ref	Serial number	Post 1000 x 5 minute cycles 104 °F (40 °C)	Post 1150 x 5 minute cycles at 140 °F (60 °C)	Post 18 x 5 minute cycles at 167°F (75 °C)
J3515AF	513	Pass	Pass	Pass
J3515AF	528	Pass	Pass	Pass

The total cumulative flow throughput for each filter was 42,954 gal (162,600 L), based on a nominal maximum flow rate of 4 gal/min (15 L/min).

2.4 Conclusions

Pall QPoint Filter Capsules with QPoint Docking Station – Shower Assembly are capable of operating continually at a maximum recommended water pressure of 75 psi (approx. 5 bar) at 140 °F (60 °C) and maintain their integrity over the simulated service life. They are also able to withstand a temperature of 167 °F (75 °C) for a total cumulative period of 90 minutes over the life of the filter, as may be used during thermal sanitization regimes. Furthermore, Filter Capsules are able to withstand over 2000 on-off cycles at the maximum recommended pressure and temperature.

Part IV Extractables testing and biocompatibility

1. Extractables testing

1.1 Introduction

The aim of these tests was to evaluate the materials in contact with the fluid pathway used in the Pall QPoint Docking Station – Shower Assembly and the Pall QPoint Filter Capsule.

1.2 Summary of methods

1.2.1 BS 6920

The individual non-metallic materials in the fluid pathway of the Pall QPoint Docking Station – Shower Assembly and Filter Capsule were subjected to five tests, as described in the British Standard “Suitability of Non-Metallic Products for use in Contact with Water Intended for Human Consumption with Regard to their Effect on the Quality of the Water” (BS 6920) by an independent organization. This included testing for the impact of the filter materials on odor and flavor, appearance, cytotoxicity, growth of aquatic microorganisms and leaching of metals. The materials were held in water at the specified temperature for the specified test duration. Extracts were tested as described and conformance to the standard was assessed by comparison with control samples of the test water.

1.2.2 1935/2004

The Pall QPoint Filter Capsules and Docking Station were tested for compliance to the requirements for food contact as detailed in European Regulation (EC) Number 1935/2004. The polymeric materials of construction of these filters are made from monomers and additives listed in Annex I of Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with foodstuffs. Migration testing was performed on the components in the Pall QPoint Filter Capsule and Docking Station by an independent organization.

1.3 Conclusions

1.3.1 BS 6920 compliance

All individual non-metallic materials in the fluid pathway of the Pall QPoint Docking station – Shower Assembly and Filter Capsule meet the limits specified in BS 6920. Data is on file.

1.3.2 1935/2004 compliance

All individual polymeric materials in the fluid pathway of the Pall QPoint Filter Capsule meet the requirements of Commission Regulation (EU) 10/20119. Data is on file.

2. Biocompatibility

2.1 Introduction

The purpose of this study was to evaluate the biological compatibility of the Pall QPoint Filter Capsules. Biocompatibility was determined according to the requirements of ISO 10993-1[5].

The QPoint Filter Capsules are comprised of polyester supported polyethersulphone media. This filter pack is contained within the capsule which comprises of an inlet bowl, filter cage, closed endcap, inner shield protection component and filter outlet. Biocompatibility testing was conducted on assembled Filter Capsules of the same materials and processes of construction as QR212U or QR22U which are shown in Table 15.

Table 15. Pall QPoint Filter Capsule materials of construction

Component	Material
Inlet Bowl	Polyester containing pigment, bacteriostatic additive and opacifier
Filter Pack – support layer	Polyester
Filter Pack – membrane	Polyethersulphone
Filter Cage	Polypropylene containing pigment, bacteriostatic additive and opacifier
Closed Endcap	Polyester containing pigment, bacteriostatic additive and opacifier
Inner Shield Protection	Polypropylene containing pigment, bacteriostatic additive and opacifier
Rose Outlet	Polyester containing pigment, bacteriostatic additive and opacifier

2.2 Summary of methods

QPoint Filter Capsules are classified as surface devices with potential for breached/compromised surface contacts with prolonged contact duration according to ISO 10993-1. Accordingly, cytotoxicity, sensitization, and irritation or intracutaneous reactivity tests are appropriate.

2.2.1 Cytotoxicity

This study evaluated the biological reactivity of a mammalian cell culture in response to extracts derived from QPoint Filter Capsule materials according to ISO 10993-5[7]. The response of a cell monolayer after exposure to the extracted material for 48 hours was observed using a light microscope.

2.2.2 Skin sensitization

This study evaluated the allergic potential of the QPoint Filter Capsule according to ISO 10993-10[8]. QPoint Filter Capsules were extracted into 0.9 % sodium chloride or cottonseed oil. Extracts were injected intradermally and topical applications also made. Skin was examined for reaction.

2.2.3 Irritation or intracutaneous injection

This study evaluated the potential for the QPoint Filter Capsule to cause irritation according to ISO 10993-10[8]. QPoint Filter Capsules were extracted into 0.9 % sodium chloride or cottonseed oil. Extracts were injected intracutaneously and sites examined for erythema and edema.

2.3 Results

The Pall QPoint Filter Capsule passed all tests specified.

2.4 Conclusions

Pall QPoint Filter Capsules meet the relevant requirements of ISO 10993.

Part V Evaluation of shelf life

1.1 Introduction

The purpose of this test was to confirm the shelf life of the Pall QPoint Filter Capsule.

1.2 Summary of methods

Gamma irradiated QPoint Filter Capsules along with the unit packaging were examined after accelerated ageing to ensure no functional degradation to the packaging or the capsule had occurred. Integrity of the packaging was examined using a dye test while Filter Capsules were integrity tested before and after a hot water flush at 140 °F at 75 psi (60 °C at 5 bar) for 500 minutes followed by 167 °F at 75 psi (75 °C at 5 bar) for 90 minutes.

Articles under test were placed in a 140 °F (60 °C) oven for 114 days to accelerate aging. This is equivalent to 5 years in real time. Test work has been conducted on Filter Capsules with the same sterilizing grade media construction as QR212U and QR22U and unit packaging of the same materials and processes of construction and sealing.

1.3 Results

1.3.1 Filter Capsule unit packaging

The unit packaging was found to be integral on products that had undergone accelerated ageing equivalent to 5 years storage.

1.3.2 Filter Capsule

Filter Capsules retained their integrity after accelerated ageing equivalent to 5 years storage post sterilization.

4. Conclusions

Pall QPoint Water Filter Capsules can be stored for 5 years following gamma irradiation and remain functional with respect to product and packaging.

Part VI References

1. American Standard Test Method (ASTM) F838-05 “Determining Bacterial Retention of Membrane Filters Utilised for Liquid Filtration”.
2. ISO 22196:2011. Measurement of antibacterial activity on plastics and other non-porous surfaces.
3. BS 6920. Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water.
4. Regulation (EC) Number 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
5. ISO 10993-1:2009. Biological evaluation of medical devices – Part 1. Evaluation and testing within a risk management process
6. HIMA Document No.3, Vol 4 “Microbiological evaluation of filters for sterilising liquids”.
7. ISO 10993-5:2009. Biological evaluation of medical devices – Part 5 Tests for *in vitro* cytotoxicity
8. ISO 10993-10:2010. Biological evaluation of medical devices – Part 10 Tests for irritation and skin sensitization
9. Commission Regulation (EU) number 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

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