

Hall Pyke



Polyfil™ II

Validation Guide

The SMART choice for filtration

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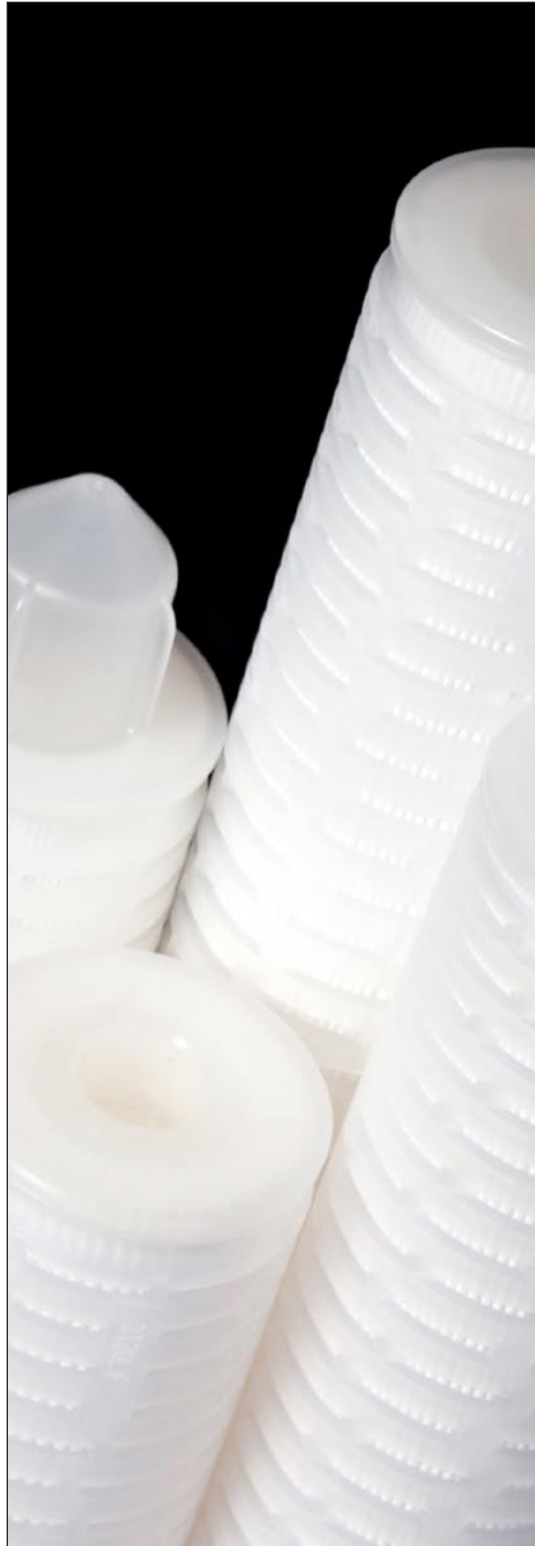
Introduction

The **Porvair Filtration Group** Polyfil™ II range of cartridge filters has been designed to meet the requirements of the most critical users of polypropylene filters for the microfiltration of liquids and gases.

Manufactured from 100% FDA approved polypropylene (except for the FDA approved seals) with fusion bonding techniques, they offer high dirt holding capacity together with accurate and reliable filtration at the rated micron size (from 0.5 to 90 microns absolute beta 5000). This Validation Guide demonstrates the high performance of the Polyfil II range and the rigorous testing that has gone into the design and manufacture of these cartridges.

Porvair Polyfil™ II cartridges are manufactured using up to five layers of graded polypropylene melt spun or spun bonded media, pleated to optimise the filtration area and minimise pleat deformation and fusion bonded into a pure polypropylene cartridge. The absence of any adhesives results in extremely low extractables and simplifies the assessment of chemical compatibility.

The cartridges are made from one or more modules, fusion bonded with adaptors to suit most filter housings. Standard cartridges incorporate injection moulded sleeves and are steam sterilisable.



Polyfil™ Materials of Construction

Porvair Polyfil™ II cartridges are constructed in a clean room under tightly controlled conditions using advanced, highly specialised machinery. Quality and consistency of product is assured by the quality control and manufacturing procedures, which are in place throughout all stages of manufacture.

Polyfil™ II components meet latest EC Directives for food contact.

Component	Materials of Manufacture	FDA Number
Core	Polypropylene	21CFR177.1520
Sleeve	Polypropylene	21CFR177.1520
Adaptors	Polypropylene	21CFR177.1520
End Caps	Polypropylene	21CFR177.1520
End Caps	Polypropylene	21CFR121.2501
Seals	Typically Silicone	21CFR177.2600
Media	Polypropylene	21CFR177.1520
Support Materials	Polypropylene	21CFR177.1520

Cartridge Dimensions (Nominal)

Diameter: 70mm (2.8")
Length: 127mm (5")
254mm (10")
508mm (20")
762mm (30")
1016mm (40")

Maximum Differential Pressure

Normal flow direction at:

20°C (68°F): 6.0bar (87lb/in²)
80°C (176°F): 4.0bar (58lb/in²)
100°C (212°F): 3.0bar (43lb/in²)
120°C (248°F): 2.0bar (29lb/in²)
125°C (257°F): 1.5bar (22lb/in²)

Reverse flow direction at:

20°C (68°F): 2.1bar (30lb/in²)
80°C (176°F): 1.0bar (15lb/in²)
100°C (212°F): 0.5bar (7lb/in²)

Based on cyclic exposure to hot air and steam Polyfil™ II cartridges are able to maintain integrity for an extended period of time at 80°C (176°F).

Product Traceability

Every Polyfil™ II filter cartridge has a batch number stamped on the outer sleeve. This batch number, along with product code and general description is shown on the protective polythene bag in which the filter cartridge is sealed, and also on the outer surface of the final product packaging.

Particle Retention Ratings

Porvair Polyfil™ II cartridges are constructed using technically advanced, carefully specified, high quality media. Up to five layers are pleated together with experimentally optimised irrigation/support materials and pleat geometry. Some of the layers may also be laminated and or calendered, thus increasing the dirt holding capacity and efficiency.

The composite graded media packs for each rating have been designed through intensive iterative testing for efficiency and life to provide the best possible performance at repeatable and dependable absolute ratings. Some competitors rate their cartridges nominally so this data is presented for comparison. This data was compiled using ISO test dust in a single pass OSU-F2 modified test rig with PMS Liquilaze laser particle counters.

Particle Removal Efficiency

Product Code	Absolute Rating 99.98% beta 5000 (microns)	Nominal Rating 99.9% beta 1000 (microns)	Nominal Rating 99.0% beta 100 (microns)	Nominal Rating 98.0% beta 50 (microns)	Nominal Rating 90.0% beta 10 (microns)
PP5	0.5	0.45	0.35	<0.3	-
PP8	0.8	0.6	0.4	0.35	<0.3
P01	1.0	0.9	0.55	<0.5	-
P02	2.0	1.7	1.2	1.0	<0.5
P03	3.0	1.75	1.2	1.0	<0.5
P05	5.0	2.6	1.25	1.0	-
P07	7.0	5.0	2.0	-	-
P10	10.0	8.0	7.5	5.0	1.5
P15	14.0	11.0	9.0	7.0	2.0
P20	17.5	12.5	10.0	7.5	<5
P30	30.0	20.0	13.0	11.0	7.0
P40	35.0	30.0	20.0	15.0	9.0
P60	60.0	55.0	50.0	37.0	24.0
P90	90.0	85.0	60.0	45.0	25.0

Tests for Biological Safety

USP Toxicity Test (1)

Porvair Polyfil™ II cartridges are manufactured using FDA approved materials, as listed above and in addition, components have been tested independently by UBTL Inc., 520 Wakara Way, Salt Lake City, Utah, USA. The results of the biological tests for plastics were that the components of construction were non-toxic.

Laboratory Number	60172
Sample Source	Porvair Filtration Group Ltd.
Material Identification	P02S1CB-02ACW5
Test Required	USP Toxicity Class V-121C
Type of Test	Systemic Injection
Reference	USP XXI
Mice	ICR Swiss Webster

Extract	Weight	Number	Animals Showing Signs of Toxicity				
			0 hours	4 hours	24 hours	48 hours	72 hours
Controls							
Saline	17-23	5	0	0	0	0	0
EtOH 5%	17-23	5	0	0	0	0	0
Oil	17-23	5	0	0	0	0	0
Peg 400	17-23	5	0	0	0	0	0
Test Samples							
Saline	17-23	5	0	0	0	0	0
EtOH 5%	17-23	5	0	0	0	0	0
Oil	17-23	5	0	0	0	0	0
Peg 400	17-23	5	0	0	0	0	0

Conclusion

No toxicity noted systematically: Non-toxic

USP Toxicity Test (2)

Laboratory Number	60173
Sample Source	Porvair Filtration Group Ltd.
Test Requested	USP Toxicity Class V-121C
Type of Test	Type B Intracutaneous
Sterilised by	88/12 Ethylene Oxide

Extract	Test/Control Rabbit #	Sites	Average Score		
			24 hours	48 hours	72 hours
Saline	Test T421	10	0	0	0
	Control T421	10	0	0	0
	Test T422	10	0	0	0
	Control T422	10	0	0	0
EtOH 5%	Test T433	10	0	0	0
	Control T433	10	0	0	0
	Test T437	10	0	0	0
	Control T437	10	0	0	0
Oil	Test T425	10	0	0	0
	Control T425	10	0	0	0
	Test T424	10	0	0	0
	Control T424	10	0	0	0
Peg 400	Test T426	10	0	0	0
	Control T426	10	0	0	0
	Test T427	10	0	0	0
	Control T427	10	0	0	0

Conclusion

No toxicity noted intracutaneously: non-toxic.

Physico-chemical Test

Laboratory Number	60180
Sample Source	Porvair Filtration Group Ltd.

Results

	Pass/Fail	Allowable Limits
Heavy Metals	Pass	0.0001%
Buffering Capacity	Pass	<10ml of titrant
Non-volatile Residue	Pass	<15mg
Residue on Ignition	Waive Pass*	<5mg

* The term 'waive pass' is assigned when the non-volatile residue is less than 5mg, indicating that the residue on ignition will also be less than 5mg.

Polyfil™ II Sterilisation by In-line Steam

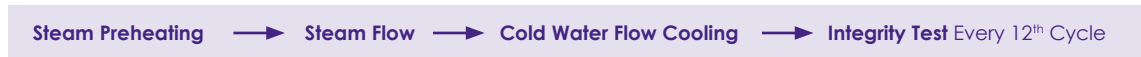
Objective

To prove the in-line multiple steaming capability of **Porvair** Polyfil™ II cartridges.

Procedure

Porvair Polyfil™ cartridges were sampled from routine production batches and integrity tested by the bubble point test method (MLP 4) prior to in-line steaming. Cartridges were subsequently steam sterilised by dynamic in-line steam at various temperatures up to 136°C (277°F) for 30 minute cycles, whilst maintaining differential pressure below 0.5bar. Upstream and downstream condensate was drained throughout each cycle. The cartridges were water cooled between each steam cycle at a flow of 10 litres per minute for 5 minutes between each cycle to simulate the highest levels of thermal shock likely to be encountered in use.

The steam sterilisation procedure is summarised as follows:



Results

Cartridge Batch Number	Number of 30 Minute Cycles	Temperature	Number Tested	Number Failed
P07 ABN 01	100	121°C (250°F)	3	0
PP8 ADD 01	100	125°C (257°F)	3	0
P01 ARF 01	80	130°C (266°F)	3	0
P01 ARF 01	70	135°C (275°F)	3	0

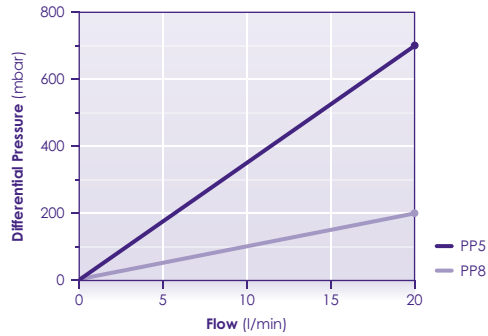
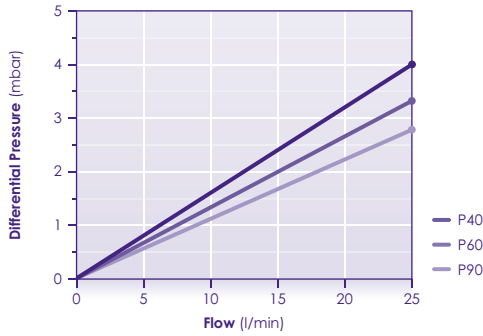
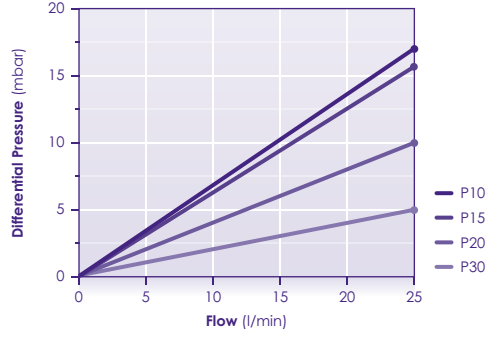
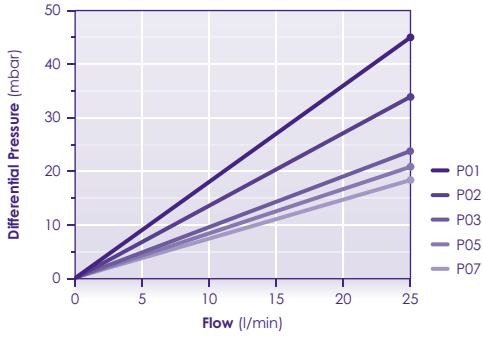
Conclusion

Porvair Polyfil™ II cartridges can be repeatedly in situ-steam sterilised up to 135°C (275°F).

Liquid Flow Rate Characteristics

Typical Clean Water Flow Rate, based on a 250mm (10") single cartridge in a **Porvair** housing, exhibits the differential pressure characteristics indicated below, for solutions with a viscosity of 1 centipoise.

Clean Water Flow Rates

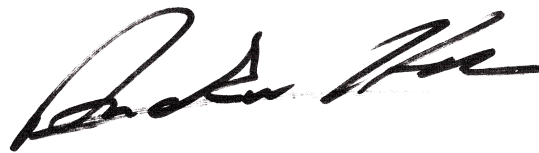


SMART Choice

To help you select the right filtration solution for your business Hall Pyke have developed our Smart Choice Catalogue. Use the catalogue to help you navigate through the often difficult and complex decisions about filtration products. The catalogue features just a selection of the filtration solutions Hall Pyke can provide. Your account manager will be happy to discuss your specific needs and answer any questions you may have.

“Having a World Class product range is at the heart of our strategy but it’s delivering first class service, tailored to our unique customer needs that’s the life blood of our organisation.

If both of these things are important to your company then Hall Pyke is the Smart Choice for filtration”.



Andrew Hall, Managing Director



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