VALIDATION GUIDE

HIGH FLOW TETPOR II

Sterilizing Grade

Cartridge Filters

Contents

1. Introduction

Sterilizing grade filters used to sterilize gases that come into contact with food or drug products must conform to strictly defined quality standards.

This validation guide provides proof of performance of HIGH FLOW TETPOR II filter cartridges with respect to bacterial retention and physical performance characteristics such as flow rates and resistance to steam sterilization. The performance tests conducted for HIGH FLOW TETPOR II products have been designed to guarantee that sterile gas will continue to be provided even under the most arduous operating conditions.

Guidelines for validation can be sourced from publications issued by the FDA, EMEA, USP, EP, BP, PDA[1], etc. This validation document has been produced with these guidelines in mind to enable the end user to incorporate this information within their own validation documentation or standard operating procedures for the process.

The performance of HIGH FLOW TETPOR II filter cartridges has been tested in accordance with - and exceeds - the specific guidelines of PDA Technical Report 40 'Sterilizing Filtration of Gases' *(Supplement Volume 58 No.S-1 Jan / Feb 2005)*. The filter also conforms to ISO 8573-7 - Compressed Air Part 7. Test Methods for viable microbiological contaminant content.

NOTE

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The Quality Assurance Department,
Parker Hannifin Manufacturing Ltd, domnick hunter Process Filtration – Europe,
Durham Road, Birtley, Co. Durham, UK, DH3 2SF
Tel: +44 (0)191 410 5121
Fax: +44 (0)191 410 5312
E-mail: dhprocess@parker.com

Registered Holder Information

Name: ……

Company: ……

Department: ……

Address: ……

……

……

Registered No. ……

Date Issued: ……

Signed ……

[1] FDA, EMEA, USP, EP, BP, PDA – Food and Drug Administration, European Medicines Evaluation Agency, United States, European and British Pharmacopoeia, Parenteral Drug Association.

2. Quality Assurance

Quality is built into all Parker domnick hunter filtration products through a rigorous product design process, careful selection of suppliers and materials, and manufacture within a highly controlled environment using validated production technologies in adherence to cGMP.

2.1. Quality and Environmental Management Systems

Parker domnick hunter is certified by Lloyds Register Quality Assurance to current versions of the following quality standards:

- BS EN ISO 9001 Quality Management Systems
- BS EN ISO 14001 Environmental Management Standard
- BS EN ISO 13485 Medical Devices

Copies of the original certificates are available upon request

2.2. Manufacturing Facilities

Parker domnick hunter continues to invest substantially in installation of the latest clean room and manufacturing technology. All manufacturing systems are validated using statistical methodologies (process, product and software) and constantly monitored using statistical process control charts. All personnel within the manufacturing operations are fully trained in cGMP and against competency frameworks to ensure their suitability to operate within specific manufacturing areas.

2.3. Material Conformity

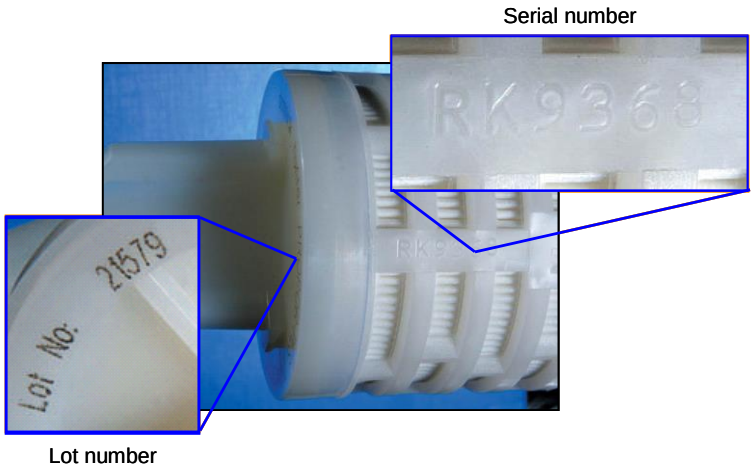
Parker domnick hunter works closely with suppliers to ensure materials supplied are of a consistently high quality and also to develop new materials as part of our ongoing product development activity. In addition to supplier certificates of conformity and analysis, incoming raw materials, including moulded parts, membranes and supports, and elastomeric seals, are subject to an appropriate level of incoming inspection. This includes bacterial challenge on each lot of membrane used in the manufacture of sterilizing grade filter cartridges.

2.4. Product and Lot Release Criteria

Prior to shipment all Parker domnick hunter cartridges undergo final product quality control. 100% of testable products undergo a non-destructive integrity test (diffusional flow). This includes a high volume flush with water that meets or exceeds the current EP and USP standards for purified water. Products are dried using HEPA filtered air and sealed in a protective polyethylene bag within the controlled manufacturing environment prior to final pack and despatch.

2.5. Product Traceability

The product code and type, lot number and unique serial number are printed on all products. Additionally, the lot number is identified on the protective bag label and the box label within which the cartridge is packed. The serial number provides complete traceability back to pleated materials used in the manufacture of each product and the manufacturing processes through the module routing sheet.



2.6. Product Shelf Life

The shelf life for HIGH FLOW TETPOR II cartridges is 5 years.

3. Product Description

All products within the HIGH FLOW TETPOR II range are fully validated to provide sterile air / gas under worst case conditions in a wide range of applications through the food & beverage, dairy and pharmaceutical industries.

This performance has been qualified under worst case condition (sterile gas system flooded with water) using the current revision of ASTM Standard Test Method F838 for sterilizing liquid filters. Their performance in gas streams has been qualified for full retention of both bacteria and bacteriophage when tested in accordance with the recommendations in PDA Technical Report 40 'Sterilizing Filtration of Gases' *(Supplement Volume 58 No.S-1 Jan / Feb 2005)*.

3.1. Materials of construction

All materials meet the FDA requirements as defined in Title 21 Code of Federal Regulations and the BioSafety Tests as defined in the current USP including the Class VI Plastics Testing.

Filtration Membrane	Polytetrafluoroethylene (PTFE)
Upstream Support	Polypropylene
Downstream Support	Polypropylene
Inner Core	316L stainless steel (polypropylene for vent autoclave)
Outer Protection Cage	Polypropylene
Endcaps	Polypropylene
Endcap Insert	Polysulfone
Standard o-rings	Silicone (EPDM for vent autoclave)
Outer protection sock (Vent autoclave only)	Polyurethane

3.2. Product Coding

Product code structures indicate the cartridge sizes, endcap configurations and o-rings that are available within the product range.

Cartridges

Example: ZHFT/2C-V 500 mm (20") HIGH FLOW TETPOR II filter cartridge, pharmaceutical grade with 'C' style endcap and viton o-rings.

ZHFT / [ ] [ ] - [ ]

Code	Length (mm)	Length (inch)	Diameter (mm)
D	35	1.5	35
C	65	2.5	35
B	65	2.5	56
A	125	5	56
K	125	5	72
1	250	10	72
2	500	20	72
3	750	30	72
4	1000	40	72

Code	10" Endcap Style
C	P-7
P	BIO-X RETROFIT
H	UF RETROFIT

Code	10" Endcap Style
H	UF RETROFIT
T	TRUESEAL
W	HF DEMI C&D
Y	DEMI MCY
Z	DEMI A&B Std

Code	o-rings
E	EPDM[2]
P	FEP Encapsulated Silicone
V	Viton[3]
S	Silicone[4]

Vent autoclave cartridges

Example: ZTA-A.01V A size vent autoclave cartridge with ½ inch BSPP connection

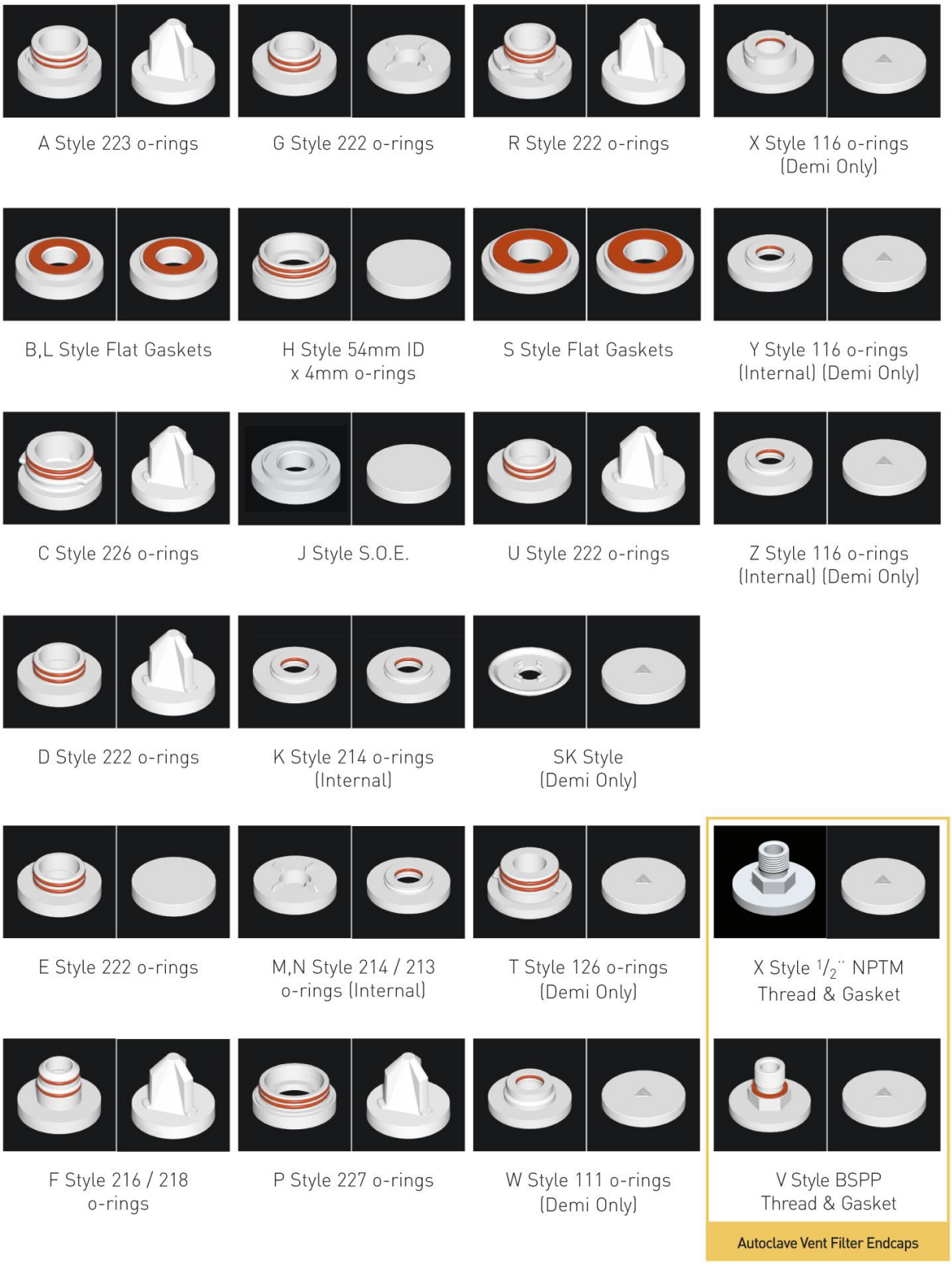
ZTA - [ ] **.01** [ ]

Code	Length (inch)	Length (mm)
A	3.46	88
B	5.98	152

Code	Endcap
V	½" BSPP
X	½" NPTM

[2] **EPDM** – Ethylene Propylene Diene Monomer Rubber
[3] **Viton** is a registered trademark of DuPont Dow Corporation
[4] Silicone o-rings are fitted as standard without having to specify the S in the code.

3.3. Cartridge Endcap Configurations



4. Product Specifications

4.1. Cartridge Operating Differential Pressures and Temperatures

To obtain representative maximum differential pressures the filter cartridge membrane was first wet out in $60{:}40_{v/v}$ IPA:Water then water was flowed through representative 10 inch cartridges at temperature to achieve the required differential pressure for 30 minutes.

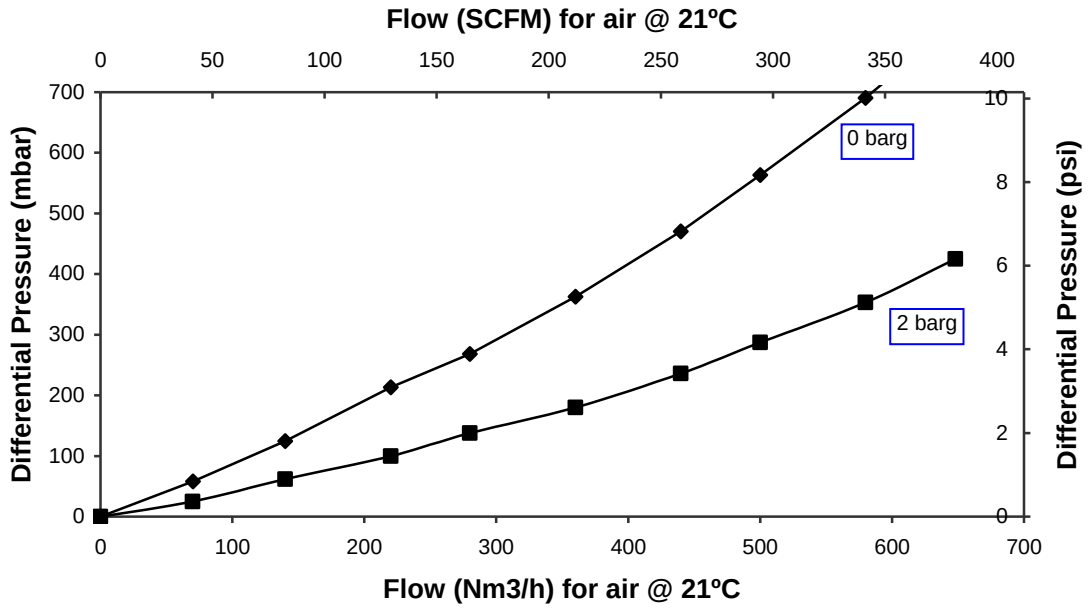
The recommended continuous maximum differential operating pressure and temperature is shown below.

Temperature		Differential Pressure Cartridges	
°C	°F	bar	psi
60	140	3.50	50.8

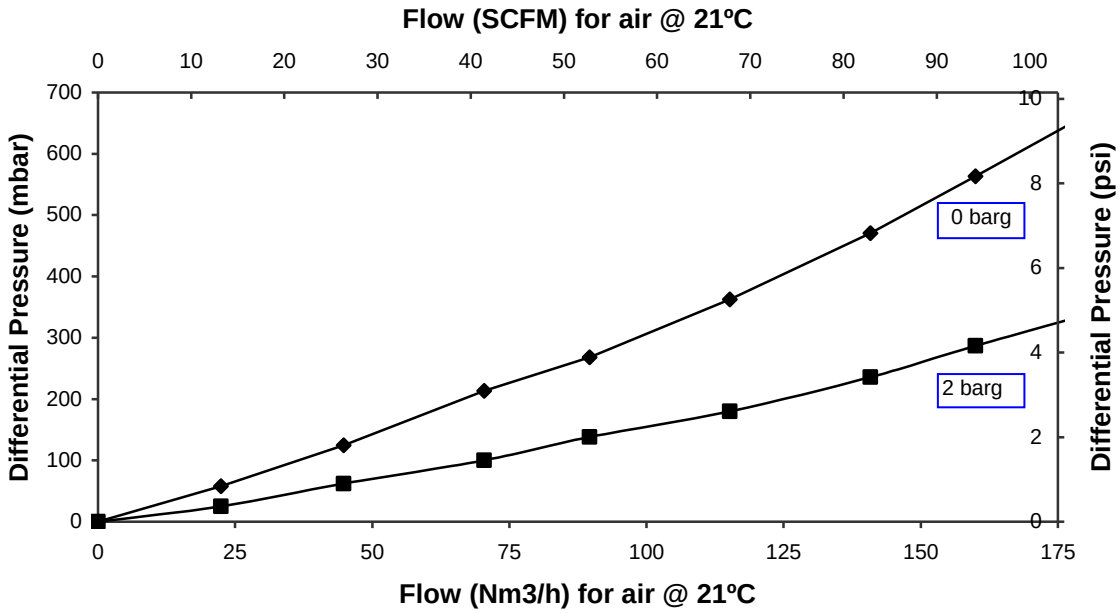
4.2. Flow Rates

Cartridge flow rates were determined for filters from three separate lots.

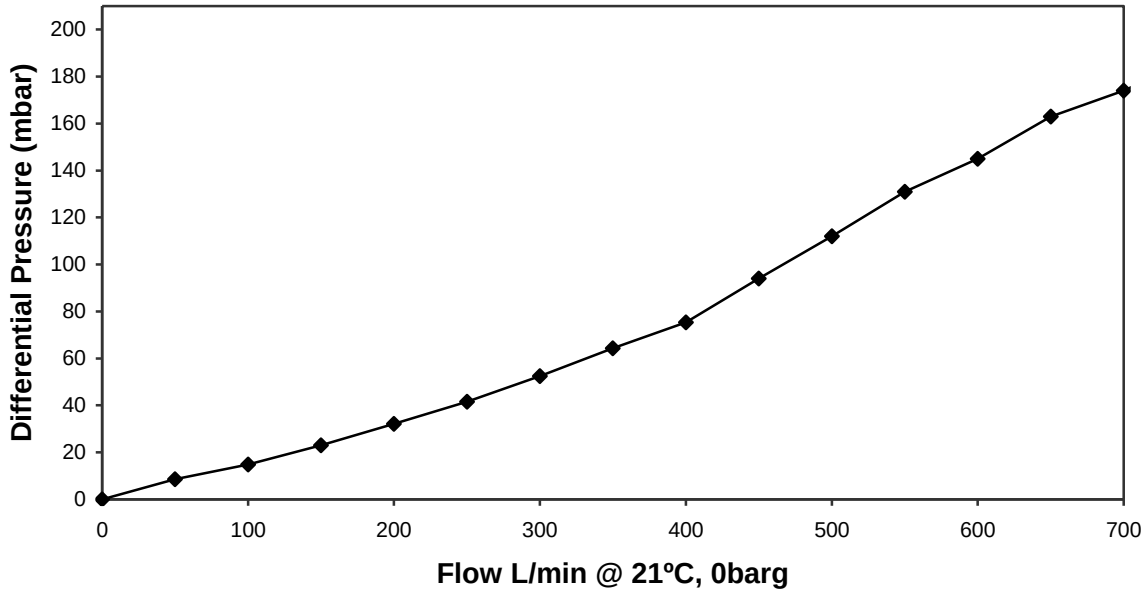
Air Flow Characteristics for 250mm (10") High Flow TETPOR II Cartridges



Air Flow Characteristics for A Size DEMI HIGH FLOW TETPOR II Cartridges



Air Flow Characteristics for A size High Flow TETPOR II Vent Autoclave Cartridge

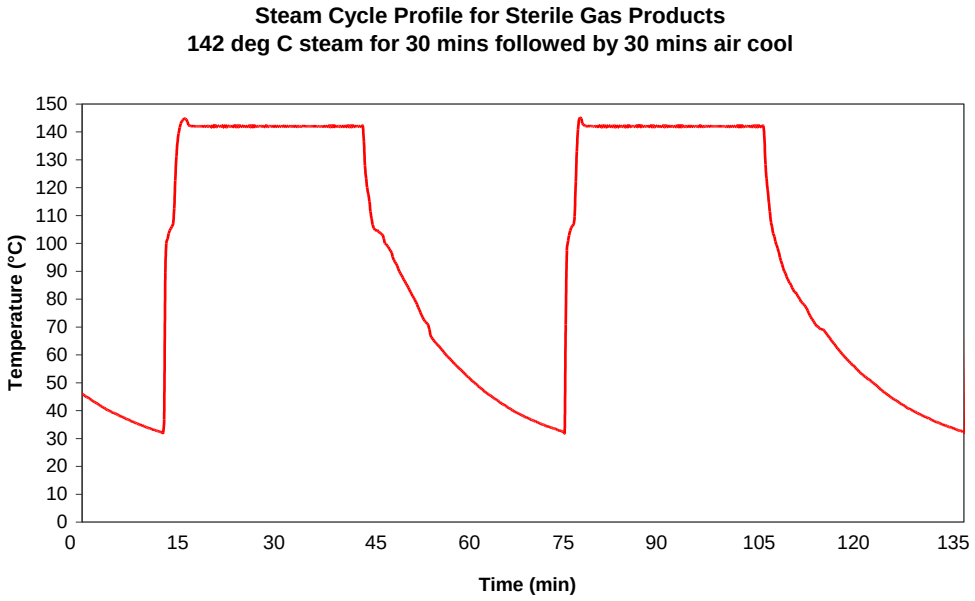


4.3. Effective Filtration Area (EFA)

Product Size	Surface Area (m^2)	Surface Area (ft^2)
B	0.10	1.08
A	0.20	2.15
K	0.30	3.23
10"	0.63	6.78
20"	1.26	13.56
30"	1.89	20.34

4.4. Steam Sterilization (Autoclaving and Steam in Place)

The steam life of cartridges was determined using the 1 hour Steam in Place (SIP) cycle which replicates extreme conditions. This includes a combination of steaming for 30 minutes at temperature followed by rapid cooling with ambient temperature compressed air for 30 minutes.



Product Format	SIP Temp °C	SIP Temp °F	Number of Cycles	Cycle Time (minutes at temperature)
Cartridges	142	288	225	30
Vent Autoclave[5]	142	288	100	30

It should be noted that the number of times the temperature is cycled from ambient to the sterilization temperature rather than the time at temperature determines the lifetime of the cartridge in steam.

To maximize the life of the cartridge, the differential pressure across the cartridge should not exceed 0.30 bar (4.4 psi) at 142°C (288°F). For new applications it is recommended that the Parker domnick hunter guidance for the method of steam sterilisation be followed.

[5] Prefilter sock must be removed from the vent autoclave format prior to steaming.

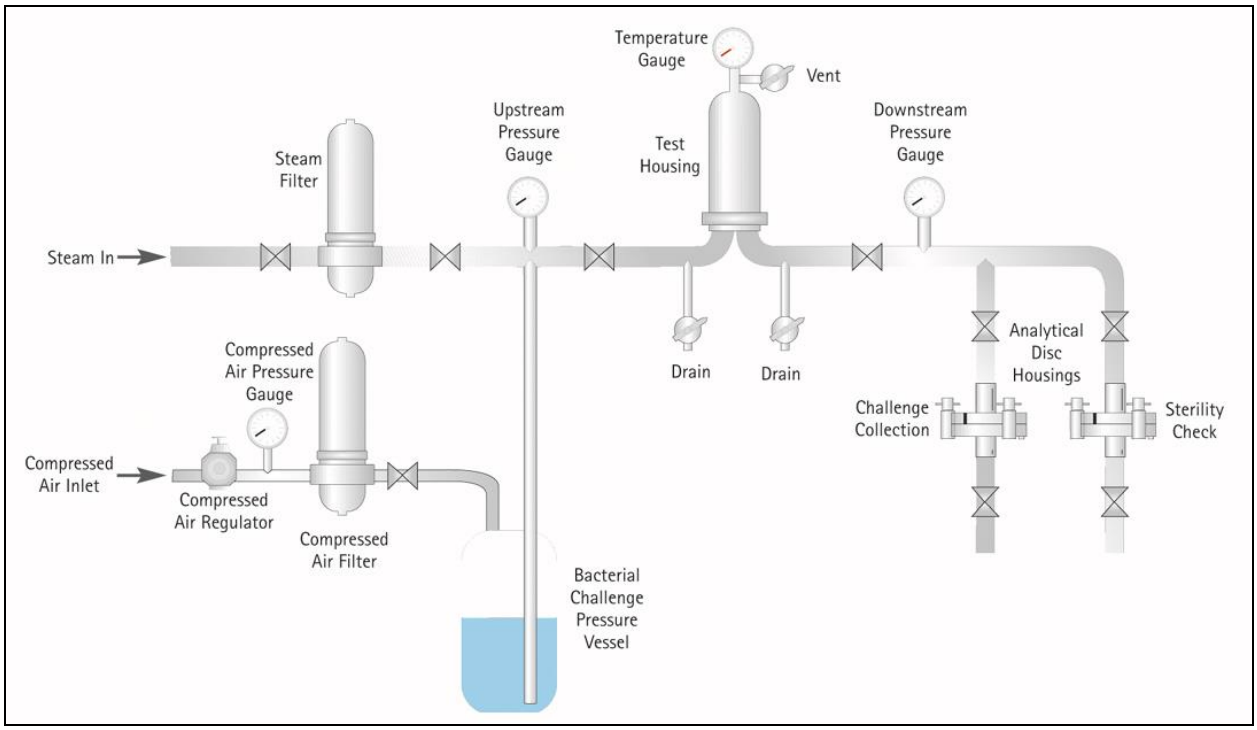
4.5. Retention

The retention of a sterilizing grade filter cartridge that may be used in the manufacture of a drug product needs to be correlated to both a liquid and gas phase challenge. Tests in the liquid phase are conducted because they are seen as worst case i.e. if the compressed air system becomes flooded with water / condensate the filter will still maintain sterility of the process. This testing is a required when the process air comes into contact with the final drug product i.e. vent filters in sterile filling lines and compressed air used in BFS equipment. The current revision of industry recognized test procedure ASTM F838 'Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration'[6] is used in this case.

To ensure the filter is capable of sterilizing in the gas phase it is subjected to aerosol bacterial and bacteriophage challenges. These tests are conducted in line with the guidelines published in PDA Technical Report 40 'Sterilizing Filtration of Gases' *(Supplement Volume 58 No.S-1 Jan / Feb 2005)*.

4.6. Liquid Bacterial Challenge

Liquid Bacterial Challenge Schematic



Under these test conditions, the test filter is challenged with a minimum of 10^7 viable *Brevundimonas diminuta* (ATCC 19146) per square centimetre of effective filtration area. Any organisms that pass through the test filter are collected and cultured on the surface of analytical discs. In this way colonies may be counted and bacterial species identified. The filter retention is quantified by expressing the filter's efficiency to remove the challenge organism from the challenge suspension as a Log Reduction Value (LRV).

$$LRV = Log_{10} \left({}^{\text{Number of organisms in the challenge}} / _{\text{Number of organisms in the filtrate}} \right)$$

[6] Previous reference to the guidance document *Microbial Evaluation of Filters for Sterilizing Liquids*, HIMA Document No. 3 Vol. 4, April 1982, referred to in USP<1211> *Sterilization by Filtration* has been superseded by the equivalent ASTM F838.

4.7. Diffusional Flow Correlation Data

The correlation between diffusional flow and bacterial challenge for HIGH FLOW TETPOR II cartridges is shown in the table below. This data shows that a 250mm (10") HIGH FLOW TETPOR II filter exhibiting a diffusional flow of <33.8 ml/min when completely wet with 60:40$_{v/v}$ IPA:Water at a test pressure of 0.8 barg (11.6 psig) at 20°C (68°F) will produce a sterile filtrate.

Filter type: ZHFT/1C HIGH FLOW TETPOR II 10" cartridge

Challenge organism: *Brevundimonas diminuta* (ATCC 19146)

Serial No.	Diffusional Flow (Air in 60:40$_{v/v}$ IPA:Water) @ 0.80 barg (11.6 psig) *ml/min*	Challenge Level (x 10^{11})	Organisms Passed	LRV[7]
ME3035	1.2	3.22	0	11.51
ME4585	6.2	3.88	0	11.59
ME3033	6.6	3.62	0	11.56
ME4571	6.9	2.40	0	11.38
ME6503	7.6	2.44	0	11.39
ME6480	8.2	3.60	0	11.56
ME4578	8.5	2.20	0	11.34
ME4575	8.7	2.34	0	11.37
ME4562	9.1	8.30	0	11.92
ME4561	9.8	1.10	0	11.04
ME4580	12.6	4.68	0	11.67
ME4293	17.0	0.87	0	10.94
ME3037	25.6	2.68	0	11.43
ME4286	27.8	1.00	0	11.00
ME4584	30.7	7.08	0	11.85
ME4566	33.8	3.82	0	11.58
ME4579	34.8	1.61	50	9.52
ME3036	38.3	4.08	13	10.54
ME4552	57.6	1.55	12	10.11
ME4574	74.4	1.66	TNTC	<7.00
ME4553	100.8	4.00	TNTC	<7.00
ME4556	188.8	3.82	0	11.58

Conclusion

A maximum diffusional flow of 16.5 ml/min for a 60:40$_{v/v}$ IPA:Water wetted 10" HIGH FLOW TETPOR II filter cartridge provides complete assurance of a sterile effluent incorporating, as it does, a safety margin in relation to the correlation data above.

[7] Where Organisms passed = 0, LRV is stated as *greater than*. TNTC : Too Numerous To Count

4.8. Water Intrusion Correlation Data

The correlation between water intrusion and bacterial challenge for HIGH FLOW TETPOR II cartridges is shown in the table below. This data shows that a 250mm (10") HIGH FLOW TETPOR II filter exhibiting a water intrusion value of <16.5 ml / 10 min at a test pressure of 2.50 barg (36.3 psig) at 20°C (68°F) will produce a sterile filtrate.

Filter type: ZHFT/1C HIGH FLOW TETPOR II 10" cartridge

Challenge organism: *Brevundimonas diminuta* (ATCC 19146)

Serial No.	Water Intrusion @ 2.50 barg (36.3 psig) ml/10min	Challenge Level (x 10^{11})	Organisms Passed	LRV[8]
ME4576	5.1	3.50	0	11.54
ME4585	5.4	3.88	0	11.59
ME6480	5.7	3.60	0	11.56
ME4551	6.0	4.84	0	11.68
ME6503	6.3	2.44	0	11.39
ME3035	7.4	3.22	0	11.51
ME3033	8.7	3.62	0	11.56
ME3034	9.2	4.30	0	11.63
ME4562	9.3	8.30	0	11.92
ME4561	9.6	1.10	0	11.04
ME3039	9.7	3.58	0	11.55
ME4580	9.9	4.68	0	11.67
ME4570	10.8	3.50	0	11.54
ME4581	14.1	2.08	0	11.32
ME3037	14.4	2.68	0	11.43
ME4584	16.5	7.08	0	11.85
ME3036	18.3	4.08	13	10.54
ME4566	18.6	3.82	0	11.58
ME4552	22.2	1.55	12	10.11
ME4574	30	1.66	Confluent	<7.00
ME4553	32.1	4.00	TNTC[9]	<7.00
ME4556	38.4	3.82	0	11.58

Conclusion

A maximum water intrusion value of 13.5 ml / 10 min for a 10" HIGH FLOW TETPOR II filter cartridge provides complete assurance of a sterile effluent incorporating, as it does, a safety margin in relation to the correlation data above.

[8] Where Organisms passed = 0, LRV is stated as *greater than*.
[9] TNTC: Too numerous to count

4.9. Integrity Testing Data

The following integrity test limits have been determined from the 10 inch cartridge correlation data. Limits for other sizes have been calculated directly from effective filtration area ratios for each variant. Diffusional flow and bubble point values are given for cartridges wetted in 60:40$_{v/v}$ IPA : Water solution using air as the test gas.

Micron Rating	Minimum Bubble Point[10]		Diffusional Flow Test Pressure		Maximum Diffusional Flow (ml/min)					
Liquid / Gas	bar	psi	bar	psi	10"	K	A	B	C	D
0.20 / 0.01	1.0	14.5	0.80	11.6	16.5	7.7	5.6	2.8	1.1	0.6

		Water Intrusion Test Pressure		Maximum Water Intrusion (ml/10min)					
		bar	psi	10"	K	A	B	C	D
		2.50	36.3	13.5	6.4	4.6	2.3	N/A	N/A

		Water Intrusion Test Pressure		Maximum Water Flow (µl/10min)[11]					
		bar	psi	10"	K	A	B	C	D
		2.50	36.3	3857	1828	1314	657	N/A	N/A

4.10. Retention to Aerosolized *Brevundimonas diminuta*

Tests have shown that HIGH FLOW TETPOR II filters are fully retentive to aerosolized *Brevundimonas diminuta* (ATCC 19146) bacteria when challenged with a total of $2x10^{11}$ cfu over a 1-hr test at the rated flow of the cartridge.

No penetration was detected, which is equivalent to a log reduction value (LRV) of >8 per cm^2 of effective filtration area.

[10] Parker domnick hunter does not recommend the use of bubble point as an integrity test method for cartridges, but values are given for use as an indicator of product integrity.

[11] Values given for Water Flow (µl/10mins) and Water Intrusion (ml/10mins) are expressions of the same parameter, the first being the actual change in water volume during the test, the second being the pressurized gas volume change (expressed at atmospheric pressure) as a result of this water flow.

4.11. Retention of Aerosolized Bacteriophage

Independent tests have shown that HIGH FLOW TETPOR II filters are fully retentive to aerosolized *MS-2 Coliphage* when challenged at between 4.39×10^7 and 4.69×10^7 pfu per cm^2 daily over a period of 8 days.

No penetration was detected over this time, which is equivalent to a log reduction value (LRV) of >11.5 for the 8-day period.

Day	Volume MS-2 nebulized (ml)	Total MS-2 challenge (pfu)	MS-2 (pfu) in effluent	
			Filter serial no ME4567	Filter serial no ME4572
1	5.55	3.83×10^{11}	ND[12]	ND
2	5.09	3.51×10^{11}	ND	ND
3	5.32	3.67×10^{11}	ND	ND
4	5.23	3.61×10^{11}	ND	ND
5	5.34	3.69×10^{11}	ND	ND
6	5.43	3.75×10^{11}	ND	ND
7	5.41	3.74×10^{11}	ND	ND
8	5.13	3.54×10^{11}	ND	ND

[12] None detected (i.e. less than 1 pfu, or less than background level)

5. Chemical Compatibility

The following data is indicative of HIGH FLOW TETPOR II cartridge compatibility with a range of chemicals at ambient temperature and 72 hour exposure. However it is recommended that specific process conditions are reviewed with your local Parker domnick hunter representative.

	ASYPOR	BIO-X II	HIGH FLOW BIO-X	HIGH FLOW BIO-X VENT AUTOCLAVE	HIGH FLOW PREPOR GF/A	HIGH FLOW TETPOR II	HIGH FLOW TETPOR H.T.	HIGH FLOW TETPOR VENT AUTOCLAVE	PEPLYN PLUS & PEPLYN PLUS DC	PREPOR GF	PREPOR PES	PROPOR PES / FS	TETPOR AIR	TETPOR LIQUID	TETPOR PLUS	EPDM 'O-Ring	VITON 'O-Ring	SILICONE 'O-Ring
Acetic acid 3.5N	LC	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Acetic acid 8.75N	LC	C	C	-	C	C	C	C	C	C	-	-	C	C	C	LC	LC	NC
Acetic acid conc.17.5N	NC	C	C	-	C	C	C	C	C	C	-	-	C	C	C	LC	NC	NC
Acetone	NC	C	C	-	C	C	C	C	C	C	NC	NC	C	C	C	NC	NC	NC
Acetonitrile	NC	C	C	-	LC	C	C	C	C	LC	-	-	C	C	C	NC	NC	NC
Acidbrite 4 (Diversey) 3.0%$_{v/v}$	NC	-	-	-	C	-	-	-	C	C	-	-	-	-	-	C	C	C
Ammonium Hydroxide 8N	NC	C	C	C	C	C	C	C	C	C	C	LC	C	C	C	C	C	C
Ammonium Oxalate 0.07N	-	C	C	C	C	C	C	C	C	C	-	-	C	C	C	C	C	C
Amyl Acetate	NC	C	C	C	LC	C	C	C	C	LC	LC	LC	C	C	C	NC	NC	LC
Aqueous Ammonia 15.5N	NC	C	C	C	LC	C	LC	C	C	LC	C	LC	C	C	C	C	C	C
Benzyl Alcohol	NC	C	C	C	NC	C	C	C	NC	NC	-	-	C	C	C	C	C	C
Benzyalkonium Chloride 0.1%	LC	C	C	C	C	C	C	C	C	C	-	-	C	C	C	C	C	C
Boric acid,saturated	C	C	C	C	C	C	C	C	C	C	-	-	C	C	C	C	C	C
Butan-1-ol	NC	C	C	C	C	LC	LC	LC	C	C	C	C	NC	NC	NC	C	C	C
Butan-2-ol	NC	C	C	C	C	C	C	C	C	C	C	C	C	C	C	LC	C	C
Carbon Tetrachloride	NC	C	C	C	NC	C	C	C	NC	NC	-	-	NC	NC	NC	NC	C	NC
Chloroform	NC	C	C	C	NC	C	C	C	NC	NC	NC	NC	NC	NC	NC	NC	LC	NC
Cyclohexane	NC	C	C	C	NC	-	-	-	NC	NC	-	-	LC	LC	LC	NC	NC	NC
1,4 – Dioxane	NC	C	C	C	LC	C	C	C	C	LC	-	-	C	C	C	NC	NC	NC
Diverflow (Diversey) 3%v/v	NC	-	-	-	NC	-	-	-	C	NC	C	C	-	-	-	C	C	LC
Diversey 212G 0.6%v/v	NC	-	-	-	C	-	-	-	C	C	-	-	-	-	-	C	C	C
Divosan Forte 0.5%v/v	LC	-	-	-	C	-	-	-	C	C	C	C	-	-	-	C	C	C
Divosan XT 1%v/v	C	-	-	-	C	-	-	-	C	C	-	-	-	-	-	C	C	C
Ethanol	NC	C	C	C	C	C	-	C	C	C	C	C	C	C	C	C	C	LC
Ethanol 45%	LC	-	-	-	C	-	-	-	C	C	C	C	C	C	C	C	C	C
Ethyl Acetate	NC	LC	LC	LC	LC	LC	LC	LC	LC	LC	NC	NC	LC	LC	LC	C	NC	LC
Formaldehyde 0.3%	LC	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Formaldehyde 37%	NC	C	C	C	C	C	C	C	C	C	-	-	C	C	C	C	C	C
Formic acid conc.	NC	C	C	C	NC	C	C	C	C	NC	-	-	C	C	C	C	NC	NC
Glycerol	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Hexane	LC	C	C	C	-	C	C	C	NC	-	-	-	-	-	-	NC	NC	NC
Hydrochloric acid 1N	C	-	-	-	C	-	-	-	C	C	C	C	C	C	C	C	C	C
Hydrochloric acid conc.	NC	-	-	-	NC	-	-	-	C	NC	-	-	C	C	C	NC	NC	NC
Hydrochloric acid conc.13%	-	C	C	C	-	C	C	C	-	-	-	-	-	-	-	NC	NC	NC
Hydrogen Peroxide	-	C	C	C	-	-	-	-	C	-	-	-	-	-	-	C	C	C
Hydrogen Peroxide 10% Volume	C	-	-	-	C	-	-	-	C	C	C	C	C	C	C	C	C	C
Hydrogen Peroxide 100% Volume	LC	-	-	-	C	C	C	C	C	C	-	-	C	C	C	C	C	C
Methanol	NC	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	NC	C
Methyl-Iso-Butylketone	NC	C	C	C	C	C	C	C	C	C	NC	NC	C	C	C	NC	NC	LC
Methylene Chloride @ 40°C	-	-	-	-	LC	-	-	-	LC	LC	-	-	-	-	-	-	-	-
Nitric acid 2N 14.4%	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	LC	C	C
Nitric acid 15.8N	NC	C	C	C	NC	C	NC	C	C	NC	-	-	C	C	C	NC	NC	NC
Ozone	-	-	-	-	-	-	-	-	-	-	NC	NC	-	-	-	-	-	-
Paraffin yellow	LC	LC	LC	LC	LC	C	C	C	C	LC	-	-	C	C	C	NC	C	NC
Pentane	LC	C	C	C	LC	-	-	-	LC	LC	-	-	LC	LC	LC	NC	C	NC
Peracetic acid 0.5% (10 wk test)	C	-	-	-	-	C	C	C	-	-	-	-	-	-	-	C	C	C
Peracetic acid 4%	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C

	ASYPOR	BIO-X II	HIGH FLOW BIO-X	HIGH FLOW BIO-X VENT AUTOCLAVE	HIGH FLOW PREPOR GFA	HIGH FLOW TETPOR II	HIGH FLOW TETPOR H.T.	HIGH FLOW TETPOR VENT AUTOCLAVE	PEPLYN PLUS & PEPLYN PLUS DC	PREPOR GF	PREPOR PES	PROPOR PES / FS	TETPOR AIR	TETPOR LIQUID	TETPOR PLUS	EPDM 'O-Ring	VITON 'O-Ring	SILICONE 'O-Ring
Perchloroethylene	-	-	-	-	-	-	-	-	-	-	NC	NC	-	-	-	-	-	-
Petroleum spirits	NC	-	-	-	NC	C	C	C	NC	NC	-	-	LC	LC	LC	NC	C	NC
Phenol (aq) 0.5N	-	C	C	C	-	NC	-	NC	-	-	-	-	-	-	-	-	-	-
Phenol 5%	NC	-	-	-	C	-	-	-	C	C	-	-	C	C	C	C	C	C
Phenol 0.25%	C	-	-	-	C	-	-	-	C	C	-	-	C	C	C	C	C	C
Polyethylene Glycol 600	NC	LC	LC	LC	NC	C	C	C	LC	NC	NC	NC	-	-	-	-	-	-
Polyglycol 2000-E	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	C	C	C
Potassium Dichromate 0.1N	LC	C	C	C	C	C	C	C	C	C	-	-	C	C	C	C	C	C
Potassium Iodine 0.6N	C	C	C	C	C	C	C	C	C	C	-	-	C	C	C	C	C	C
Potassium Hydroxide 10N	NC	C	C	C	NC	C	C	C	C	NC	C	LC	C	C	C	C	C	C
Potassium Permanganate 0.1N	NC	C	C	C	NC	C	LC	C	C	NC	C	C	C	C	C	C	C	C
Propan-1-ol	NC	C	C	C	NC	C	C	C	C	NC	C	C	C	C	C	C	C	LC
Propan-2-ol	C	C	C	C	NC	C	C	C	C	NC	C	C	C	C	C	C	C	LC
Propan-2-ol, 60:40 H_2O	C	C	C	C	NC	C	C	C	C	NC	C	C	C	C	C	C	C	C
Pyridine	NC	C	C	C	NC	C	C	C	C	NC	NC	NC	C	C	C	C	NC	C
Sodium Chloride 0.5N	LC	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Saline Lactose Broth	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Sodium Hydroxide 2N 8%	NC	NC	NC	NC	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Sodium Hydroxide 7N 28%	NC	NC	NC	NC	NC	C	C	C	C	NC	NC	NC	C	C	C	C	C	LC
Sodium Hypochlorite (14% Free Cl_2)	NC	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C
Sodium thiosulphate 0.1N	LC	C	C	C	C	C	C	C	C	C	-	-	C	C	C	C	C	C
Sulphuric acid 1N	NC	C	C	C	LC	C	C	C	C	LC	C	C	-	-	-	C	C	C
Sulphuric acid conc.	NC	NC	NC	NC	LC	LC	NC	LC	LC	LC	NC	NC	LC	LC	LC	-	-	-
Sulphurous acid	-	-	-	-	-	-	-	-	-	-	NC	NC	-	-	-	-	-	-
Toluene	-	NC	NC	NC	-	NC	NC	NC	NC	-	NC	NC	-	-	-	NC	LC	NC
1,1,1 Trichloroethane	LC	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
1,1,2 Trichloroethane	-	C	C	C	LC	C	LC	C	LC	LC	NC	NC	LC	LC	LC	NC	LC	LC
Trichloroacetic Acid 80%	LC	-	-	-	LC	-	-	-	C	LC	-	-	C	C	C	NC	LC	NC
Trichloroacetic Acid 5N	-	C	C	C	-	C	C	C	-	-	-	-	-	-	-	---		
Toluene	NC	-	-	-	NC	-	-	-	-	NC	-	-	-	-	-	NC	LC	NC
Xylene	NC	LC	LC	LC	NC	LC	LC	LC	NC	NC	LC	LC	NC	NC	NC	C	LC	NC

Chemical Compatibility User Instructions and Notes

- The chemicals are arranged in alphabetical order using their most common or trade names. If the chemical in question does not appear to be listed, it may be found elsewhere in the table under a pseudonym, in particular its IUPAC[13] name.

- **Please note:**
  - Any product that has limited compatibility (LC) at ambient temperatures should not be used at a higher temperature.
  - The list of compatibilities does not take into account any synergistic effects of more than one chemical present in the solution to be filtered.

[13] International Union of Pure and Applied Chemistry

6. Cartridge Cleanliness

HIGH FLOW TETPOR II filters must meet stringent standards to be certified pharmaceutical (P) grade product by Parker domnick hunter. One aspect of this is to confirm levels of potential contaminants that may be added to a process stream by the addition of the filter cartridge. Although this requirement is normally associated with sterile liquid filters a number of tests have been conducted to demonstrate the cleanliness of the product when in contact with some common fluids to prove acceptability in applications such as vent filtration on WFI holding tanks.

6.1. Extractables

All pharmaceutical grade filters are designed and manufactured to yield a minimum of extractables. Testing of a purified water filtrate with HIGH FLOW TETPOR II is documented below.

Test Method (1)

Non-volatile extractables from purified water samples after flowing through an autoclaved 250mm (10") HIGH FLOW TETPOR II cartridge are listed below. The levels shown are the quantities present in 100ml samples of filtrate, which were taken at stages throughout a 10-litre flush.

Cartridge Serial No. ML4583

Flush Quantity (litres)	Non-volatile Extract (mg per 100 ml)	Oxidisables (per USP 23 Test Method)
1	0.1	PASS
2	0.1	PASS
4	<0.1	PASS
6	<0.1	PASS
8	<0.1	PASS
10	<0.1	PASS

Test Method (2)

Non-volatile extractables from an autoclaved 250mm (10") HIGH FLOW TETPOR II cartridge were measured following a 4-hour dynamic immersion in a variety of commonly used solvents. The solvent volume used was 1500ml.

Solvent	Serial No. Cartridge	Weight of extract (mg)
Water @ 20^0C	FD 2999	<0.1
Water @ 80^0C	FD2995	0.1
Methanol	FD 3010	5.2
Ethanol	FD 2993	9.3
Acid (Hydrochloric solution pH 3)	FD 3007	1.8
Alkali (Ammonia solution pH 11)	FD3011	1.1
Iso Propyl Alcohol (IPA)	FD 3016	7.2

7. Tests for Biocompatibility

An independent research establishment has assessed the biological safety associated with the use of HIGH FLOW TETPOR II filters designed for processing pharmaceutical products.

The materials used in the construction of HIGH FLOW TETPOR II products meet the requirements of the current USP <88> Biological Reactivity tests at Plastics Class VI – 121ºC.

8. Certificate of Conformance

To certify that Parker domnick hunter's HIGH FLOW TETPOR II filter products meet the highest pharmaceutical quality and performance requirements, a Certificate of Conformance is issued.

Documentation Approval Section

Q.A. Approval

Approved By: Martin Newman

Title: Senior Quality Engineer

Date: February 2016

Technical Approval

Approved By: Andrew Kelly

Title: Product Manager (Life Science)

Date: February 2016

Durham Road, Birtley, Co. Durham
England, UK. DH3 2SF
Tel: +44 (0)191 410 5121
Fax: +44 (0)191 410 5312
E-mail: dhprocess@parker.com
Website: www.parker.com/processfiltration