Validation Document for TETPOR AIR Pharmaceutical Grade Cartridge and DEMICAP Capsule Filters

domnick hunter

PROCESS FILTRATION

Contents

1 Introduction

Sterilisation grade filters used to sterilise gases that come into contact with pharmaceutical products must conform to strictly defined quality standards.

By using filter technology that conforms to the standards laid down by the various certifying bodies, the quality of the final product can be assured. Contamination can also be prevented from entering the final product by its comprehensive removal at each stage of the primary and secondary process.

When sterilising grade filters are used in the manufacture of products, the interactions between product, filter and process must be fully investigated and validated.

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 instructions for the process.

This Validation Document shows that TETPOR AIR surpasses the product specification requirements that have to be imposed on sterilising grade filters.

NOTE

This Validation Document, if printed with the banner UNCONTROLLED COPY, has not been registered. If you wish to receive amendments and updates automatically, then please contact the department below or fax this page with your name and address and we will send you a registered copy: -

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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 Drugs Association.

2 Quality Policy

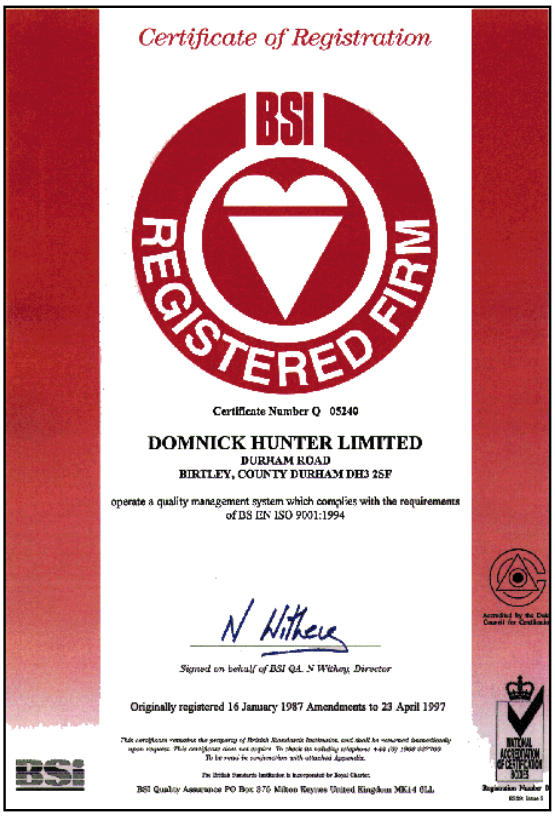
2.1 Quality Assurance

Quality is of paramount importance to domnick hunter ltd. The filtration products are manufactured under controlled environmental conditions to the highest quality regimes and are subjected to a demanding program of Quality Assurance. Inspection and test protocols are implemented from vendor assessment, specification and receipt of raw materials, through every stage of the manufacturing process culminating in a non-destructive integrity test of the filter prior to packing and release.

Every stage of the manufacturing process has well defined assembly protocols laid down thus ensuring operational repeatability.

domnick hunter's responsibility as a manufacturer of quality extends beyond the site at Birtley in the UK, through to the world-wide network of filter and separation specialists.

The Quality Assurance Department operates with a well-equipped Laboratory Services Department, in which specialised personnel are employed to perform the essential quality inspections. **domnick hunter** has been assessed by the British Standards Institution and is registered to BS EN ISO 9001:1994, which defines the standards for quality systems, model for quality assurance in design, development, production, installation and servicing. As a concerned environmentally aware manufacturer, **domnick hunter** is also audited and certified to BS EN ISO 14001:1996 for its Environmental Management System.



Certificate of Registration

BSI

REGISTERED FIRM

Certificate Number Q 05240

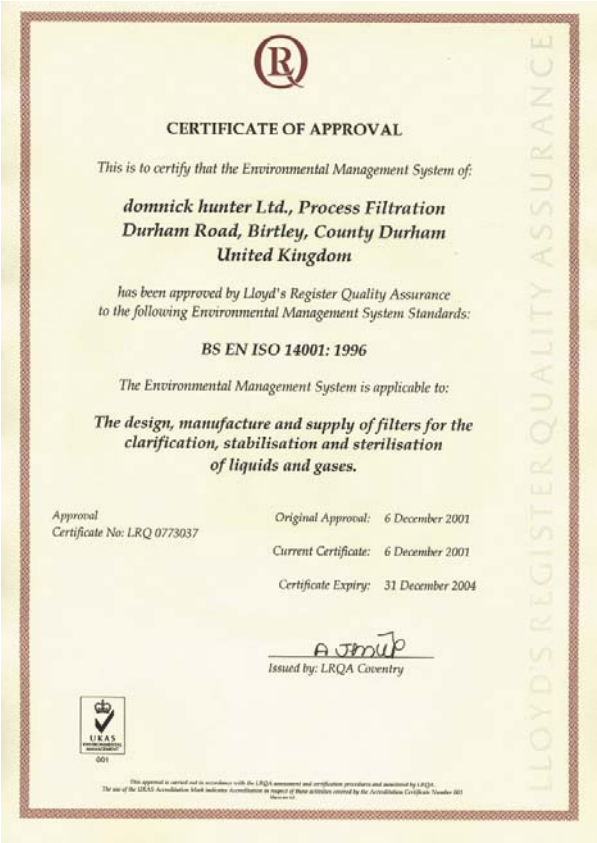
DOMNICK HUNTER LIMITED
DURHAM ROAD
BIRTLEY, COUNTY DURHAM DH3 2SF

operate a quality management system which complies with the requirements of BS EN ISO 9001:1994

Signed on behalf of BSI QA. N Withey, Director

Originally registered 16 January 1987 Amendments to 23 April 1997

BSI Quality Assurance PO Box 375 Milton Keynes United Kingdom MK14 6LL



CERTIFICATE OF APPROVAL

This is to certify that the Environmental Management System of:

domnick hunter Ltd., Process Filtration
Durham Road, Birtley, County Durham
United Kingdom

has been approved by Lloyd's Register Quality Assurance to the following Environmental Management System Standards:

BS EN ISO 14001: 1996

The Environmental Management System is applicable to:

The design, manufacture and supply of filters for the clarification, stabilisation and sterilisation of liquids and gases.

Approval
Certificate No: LRQ 0773037

Original Approval: 6 December 2001
Current Certificate: 6 December 2001
Certificate Expiry: 31 December 2004

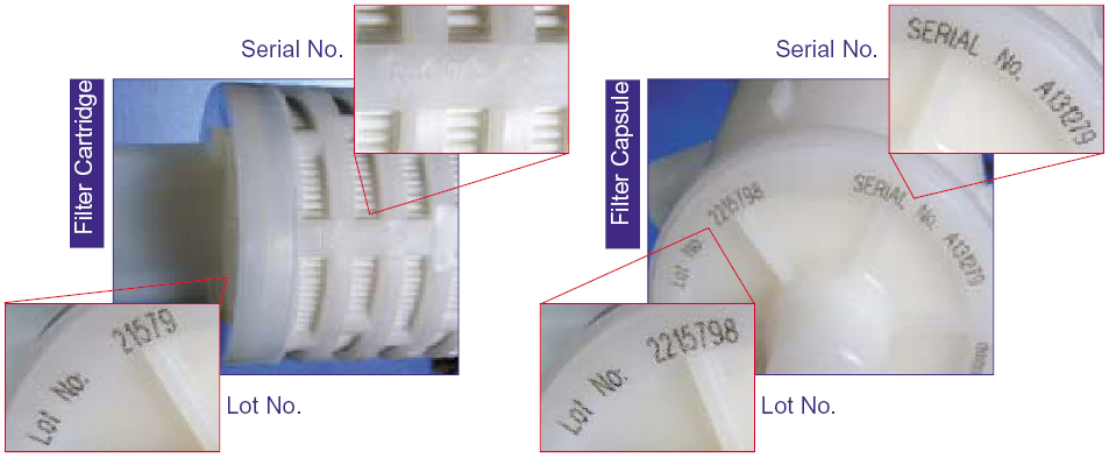
Issued by: LRQA Coventry

LLOYD'S REGISTER QUALITY ASSURANCE

3 Product Traceability

All pharmaceutical grade filters are non-destructively integrity tested and flushed with Purified Water. They are then dried using HEPA filtered air and sealed in a protective polyethylene bag within the controlled manufacturing environment prior to despatch.

To enable full traceability of all pharmaceutical grade filter products, each filter module is marked with an individual serial number. In addition, each filter product is marked with a lot number, product code and general description which is also shown on both the protective polyethylene bag in which the filter is sealed and on the outer surface of the final product packaging.



4 Summary of Test Methods

A number of the critical procedures used within this validation document are based on external methods sourced from publications issued by the USP, EP, FDA, ISO[2] and ASTM[3]. The remaining procedures are in-house methods prepared using **domnick hunter's** relevant experience and industry accepted standards in the fine filtration field. The comprehensive nature of these procedures ensures high batch to batch compliance to the specification.

Membrane Validation		**Filter Validation and Testing**				
Physical	**Chemical / Biological**	**Integrity Testing**	**Retention**	**Flow Parameters**	**Durability**	**Chemical / Biological**
Bubble Point	Chemical Compatibility	Bubble Point	Liquid Bacterial Challenge	Clean Air Flow	Max Allowable Steam life	Chemical Compatibility
Water / IPA Flow	Extractables	Pressure Hold	Particle / Fibre Shedding		Max continuous running Temperature	Extractables
Thickness	Pyrogen Extractables	Diffusional Flow			Max Allowable Differential Pressure	Bio-Compatibility
Bacterial Challenge	Oxidisables	Aerosol Challenge				Pyrogen Extractables
Burst Strength	Bio-Compatibility	Water Intrusion				Oxidisables
Autoclavability						
Pore Size Analysis						

[2] ISO – International Organisation for Standardisation
[3] ASTM – American Society for Testing and Materials

5 Preparation of Pharmaceutical Grade Filters

5.1 Pharmaceutical Grade Standard

TETPOR AIR filters must meet stringent standards to be certified P-grade product by **domnick hunter ltd**. The standards that must be met are:-

- Conformation to the requirements for non-fibre releasing filters as laid down in the United States Food and Drug Administration Regulations 21CFR211.72 and 210.3(b), (6).
- Effluent quality following a purified water flush must also be met as determined by the following tests:
  - ◊ Test for oxidisable material per USP 23 Purified Water.
  - ◊ Test for bacterial endotoxins using a gel clot LAL (Limulus Amoebocyte Lysate).
  - ◊ Test for particulates.
  - ◊ Test for TOC (Total Organic Carbon).
  - ◊ Test for Conductivity.
- All components conform to the Biological Safety Standards identified in USP <88> to Class VI-121°C levels.
- All filters must meet minimum defined integrity test values prior to despatch, defined from a correlation against an appropriate bacterial challenge.
- All filters are flushed with a high flux of purified water prior to despatch, as a guarantee of product cleanliness.

5.2 Quality of Purified Water used in the preparation of Pharmaceutical Grade Filters

The current USP and EP standards for Purified Water and Highly Purified Water specify a maximum conductivity of 1.1 µS/cm @ 20°C (68°F) and a maximum TOC (Total Organic Carbon) content of 0.5 mg (500ppb) of carbon per litre.

The water used in the flushing stages of pharmaceutical grade filters exceeds these Pharmacopoeial requirements.

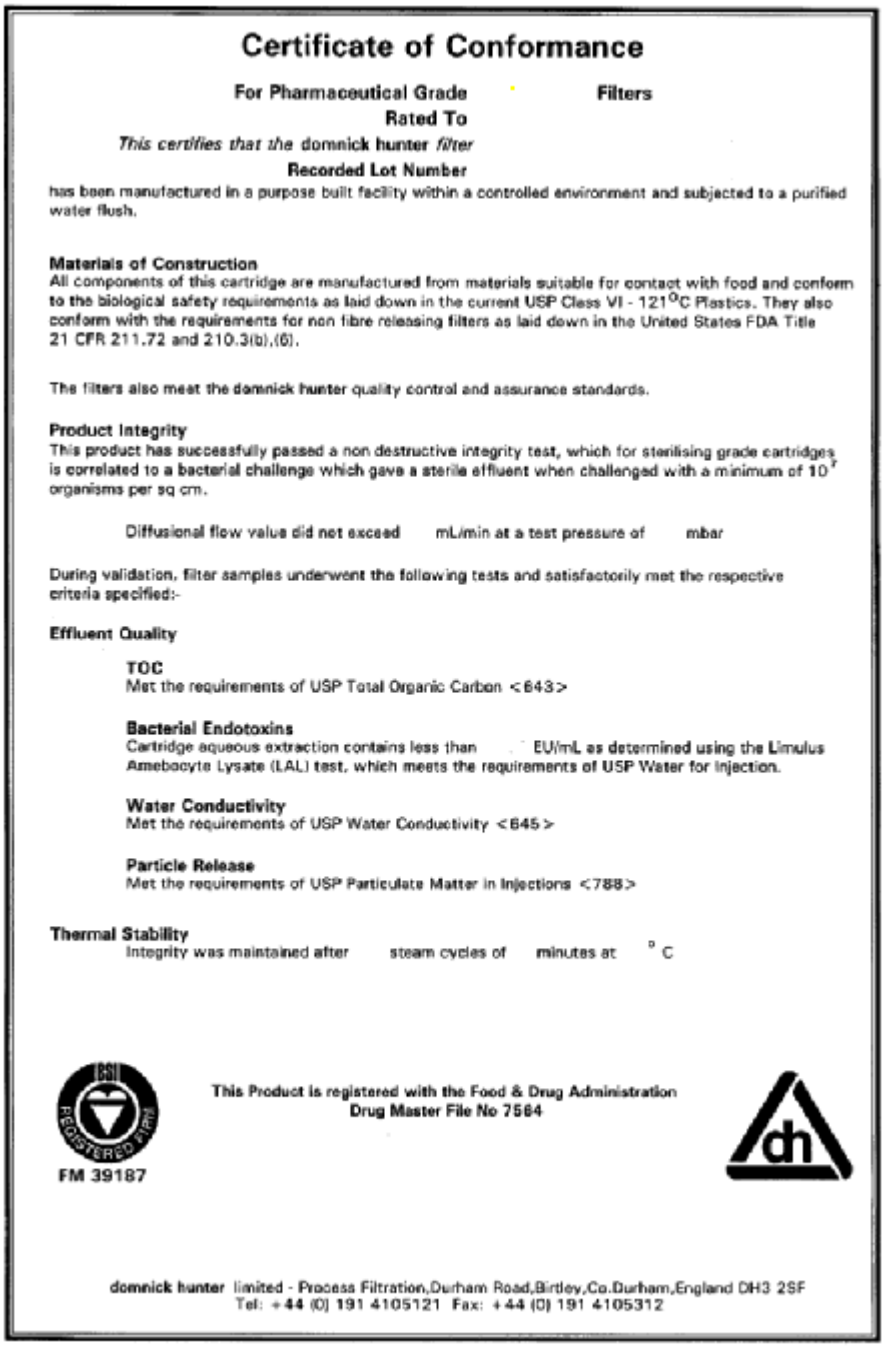
In addition, two other tests are carried out on samples taken from point of use and from a number of points in the supply pipework: -

- A Membrane Filtration Method Standard Plate Count Technique, to establish the microbial content.
- A gel clot LAL (Limulus Amoebocyte Lysate) test, for detection of bacterial endotoxins at 0.125 EU/ml sensitivity.

6 Certificate of Conformance

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

The example following is for TETPOR AIR cartridge filters.[4]



Certificate of Conformance

For Pharmaceutical Grade Filters
Rated To
This certifies that the **domnick hunter** *filter*
Recorded Lot Number
has been manufactured in a purpose built facility within a controlled environment and subjected to a purified water flush.

Materials of Construction
All components of this cartridge are manufactured from materials suitable for contact with food and conform to the biological safety requirements as laid down in the current USP Class VI - 121°C Plastics. They also conform with the requirements for non fibre releasing filters as laid down in the United States FDA Title 21 CFR 211.72 and 210.3(b),(6).

The filters also meet the domnick hunter quality control and assurance standards.

Product Integrity
This product has successfully passed a non destructive integrity test, which for sterilising grade cartridges is correlated to a bacterial challenge which gave a sterile effluent when challenged with a minimum of 10^7 organisms per sq cm.

Diffusional flow value did not exceed mL/min at a test pressure of mbar

During validation, filter samples underwent the following tests and satisfactorily met the respective criteria specified:-

Effluent Quality

TOC
Met the requirements of USP Total Organic Carbon <643>

Bacterial Endotoxins
Cartridge aqueous extraction contains less than EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test, which meets the requirements of USP Water for Injection.

Water Conductivity
Met the requirements of USP Water Conductivity <645>

Particle Release
Met the requirements of USP Particulate Matter in Injections <788>

Thermal Stability
Integrity was maintained after steam cycles of minutes at °C

FM 39187

This Product is registered with the Food & Drug Administration
Drug Master File No 7584

domnick hunter limited - Process Filtration,Durham Road,Birtley,Co.Durham,England DH3 2SF
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[4] A specific Certificate of Conformance is issued for DEMICAP capsules.

7 Product Coding and Range for TETPOR AIR Cartridges

Represented below are details of the product code structure for TETPOR AIR cartridges. This product code structure indicates cartridge sizes, micron ratings, endcap configurations and O'rings that are available within the product range.

Example: ZCMT2/-020C-A 500mm (20") 0.01 micron TETPOR AIR filter cartridge, pharmaceutical grade with 'C' style endcap and Silicone O'rings.

ZCMT [ ] / [ ][ ][ ][ ] - [ ][ ][ ]

Code	mm	Inch	Dia (mm)
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	Micron Rating
020	Liquid 0.20 Gas 0.01

Code	10" Endcap Style
B	Dh DOE
C	P-7
G	M-0
R	S-28
Code	**DEMI Endcap Style**
SK	Retrofit
T	TRUESEAL
Y	DEMI MCY
Z	DEMI A&B Std

Code	Variant Ref
A	Air

Code	O' Rings[5]
E	EPDM[6]
P	FEP Encapsulated Silicone
V	Viton[7]
S	Silicone

Code	Additional Spec

8 Product Coding and Range for TETPOR AIR Capsule Filters

Represented below are details of the product code structure for TETPOR AIR DEMICAP capsules. This product code structure indicates capsule sizes, micron ratings, connection configurations, sterility and material options that are available within the product range.

Example: ZEMTB-020TT-PN3 B-size 0.01 micron TETPOR AIR filter capsule, pharmaceutical grade with Tri-clamp connections, supplied non sterile in packs of 3.

ZEMT [ ] - [ ][ ][ ][ ][ ] - [ ][ ][ ]

Code	Dimensions
E	See diagram Section 10
B	
A	

Code	Micron Rating
020	Liquid 0.20 Gas 0.01

Code	Inlet Connection	Outlet Connection
T	1" Tri-clamp	1" Tri-clamp
N	½" NPT Male	½" NPT Male
H	½" Hosebarb	½" Hosebarb
G	Stepped 6mm – 12mm Hosebarb	Stepped 6mm – 12mm Hosebarb with filling bell
M	¼" NPT Male	¼" NPT Male

Code	Variant Ref
P	Pharmaceutical

Code	Sterilisation Grade
N	Supplied Non-sterile
S	Supplied Gamma Pre-sterilised

Code	Additional Spec
3	3 per pack

[5] Silicone O'rings are fitted as standard without having to specify the S in the code.
[6] **EPDM** – Ethylene Propylene Diene Monomer Rubber
[7] **Viton** is a registered trademark of DuPont Dow Corporation

9 Endcap Configuration Diagrams

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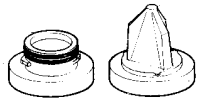
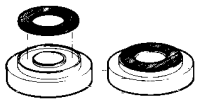
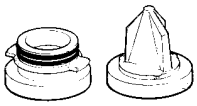
A Style
223 'O' Rings



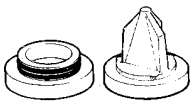
B,L Style
Flat Gaskets



C Style
226 'O' Rings

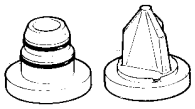


D Style
222 'O' Rings

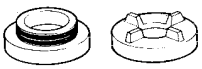


E Style
222 'O' Rings

F Style
216/218 'O' Rings



G Style
222 'O' Rings

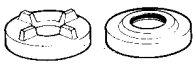


J Style
S.O.E.

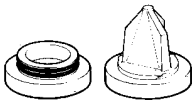
K Style
214 'O' Rings

M Style
214 'O' Rings

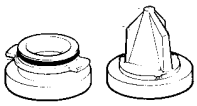
N Style
213 'O' Rings



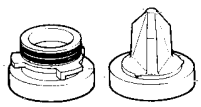
P Style
227 'O' Rings



Q Style
226 'O' Rings

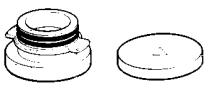


R Style
222 'O' Rings



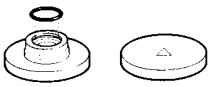
SK Style

T Style
126 'O' Rings



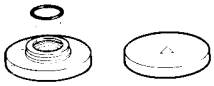
V Style
Flat Gaskets

W Style
111 'O' Rings

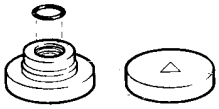


X Style
Flat Gaskets

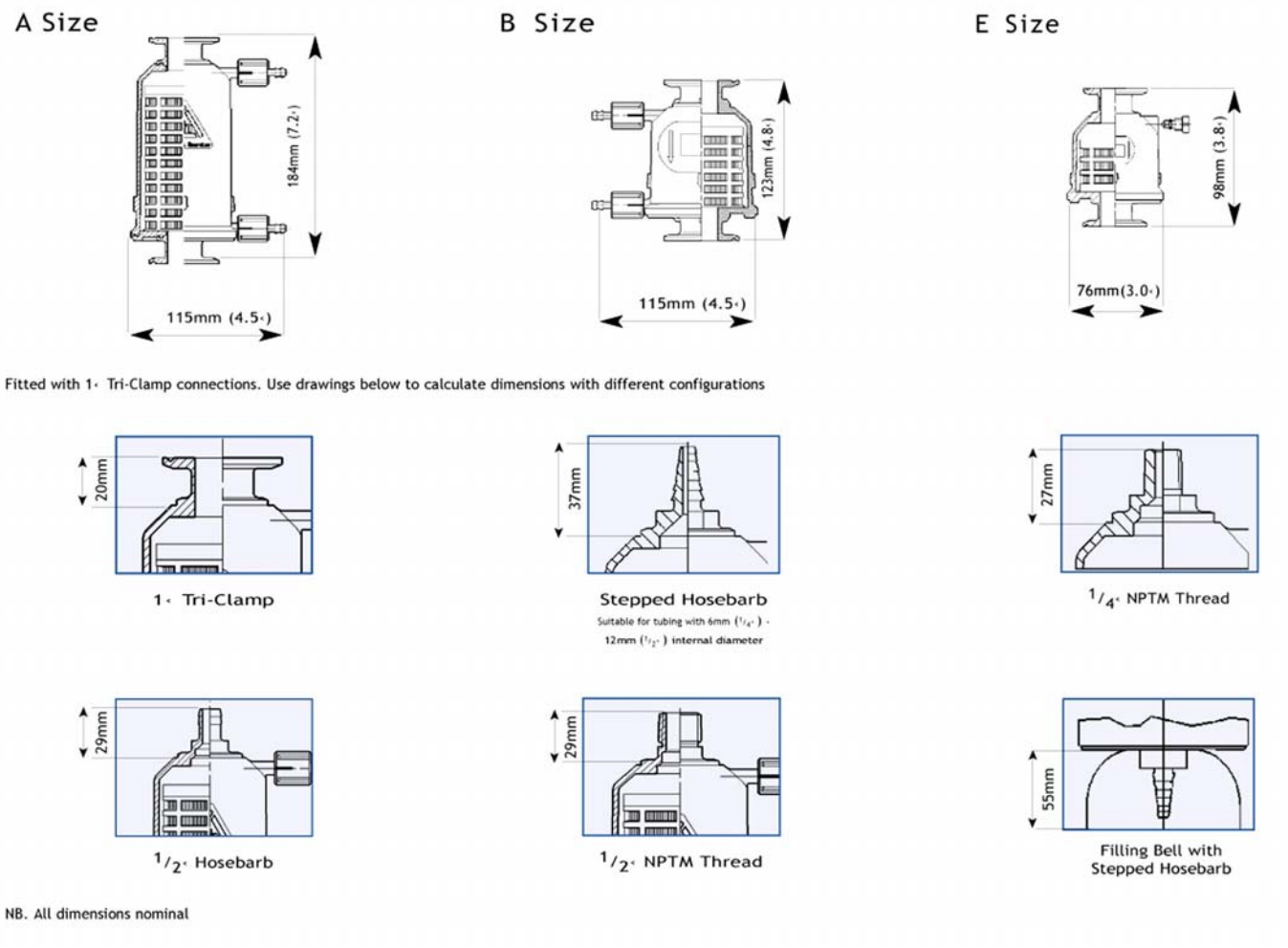
Y Style
116 'O' Rings (Internal)



Z Style
116 'O' Rings (Internal)



10 Capsule Dimensions



11 Product Specification

11.1 Application

All products within the TETPOR AIR range, cartridge, capsule and disc have been designed for use in pharmaceutical applications for sterilisation duties, evaluated using ASTM Standard Test Method F838-83, or for prefiltration applications.

11.2 Materials of Construction for TETPOR AIR Cartridges and Capsules

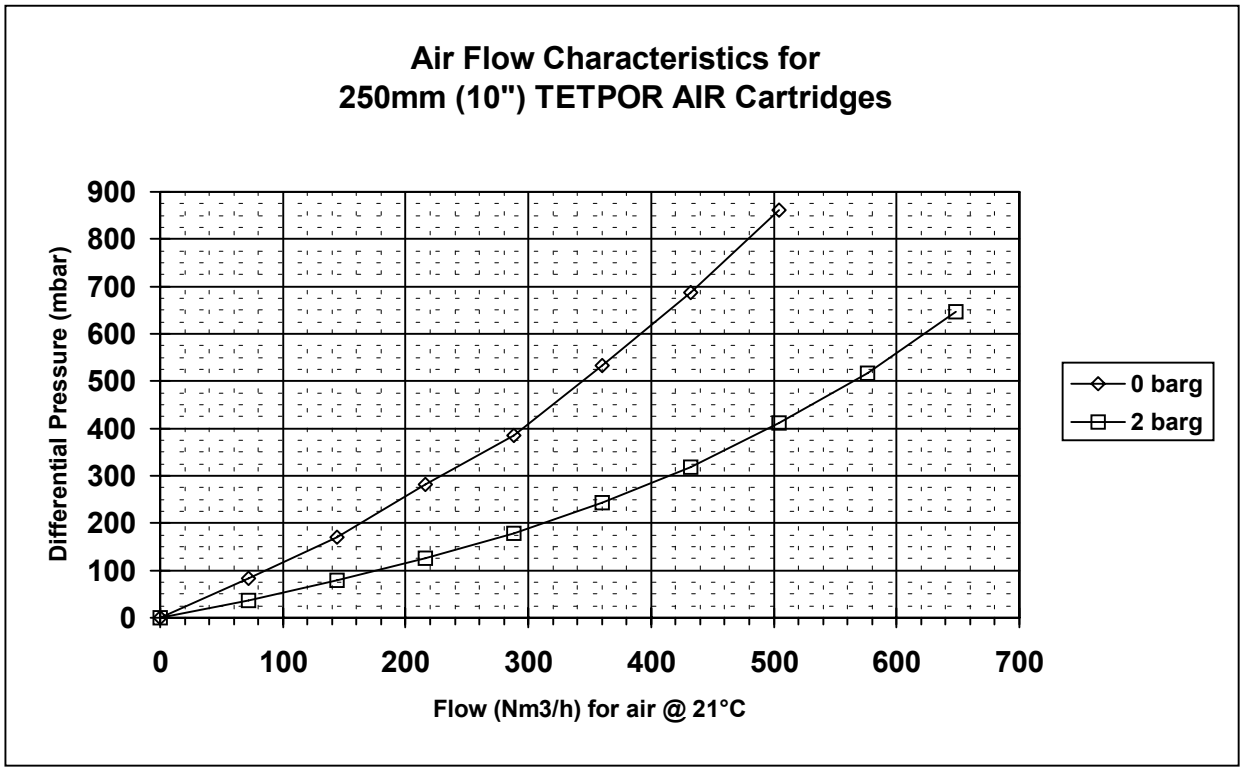
All materials used in the construction of TETPOR AIR products that have product contact have met the requirements of the current USP Biological Reactivity Tests, In Vivo to Plastics Class VI-121°C.

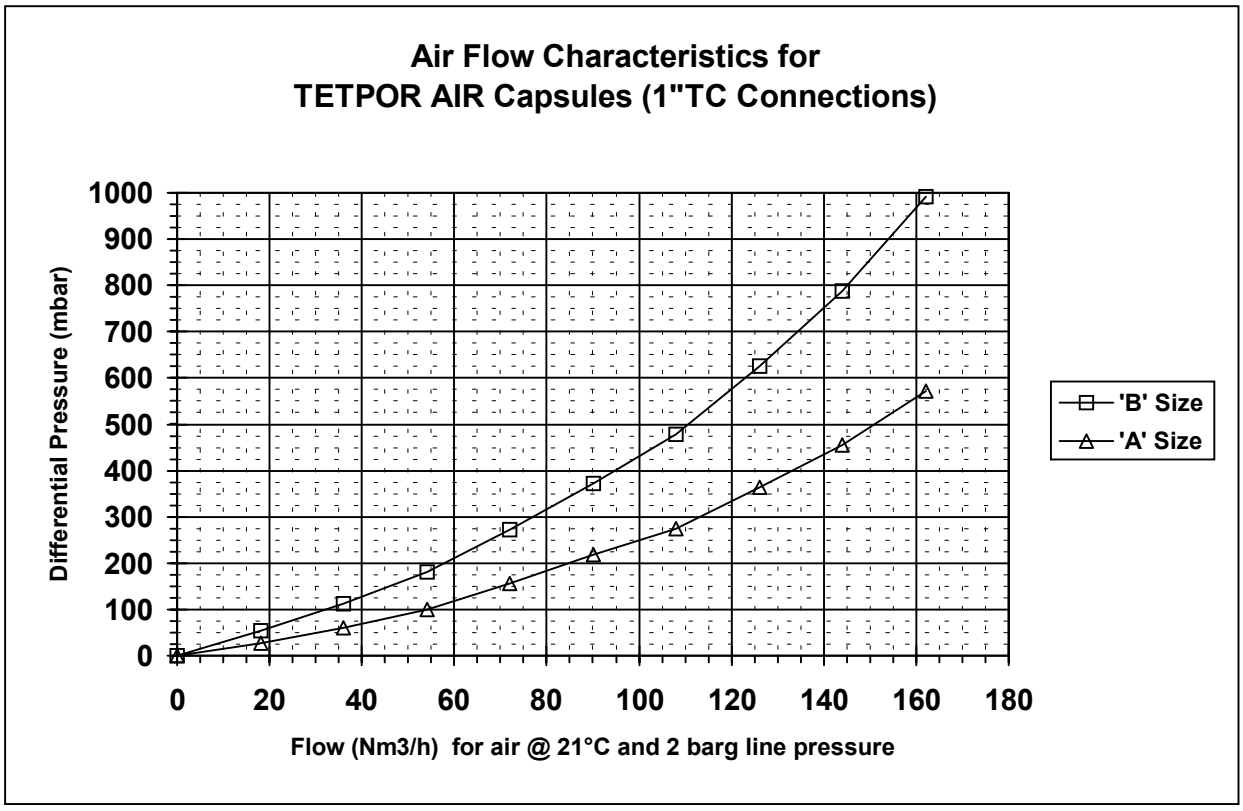
All jointed surfaces are assembled by the use of heat sealing technology. No resins or binders are used in the manufacture of the filter and no surfactants are added to aid wetting.

Component	Material of Construction
Filtration Membrane	Polytetrafluoroethylene (PTFE)
Upstream Support	Polypropylene
Downstream Support	Polypropylene
Inner Support Core	Polypropylene
Outer Protection Cage	Polypropylene
Endcaps	Polypropylene
Endcap Insert	316 Stainless Steel / Polysulphone (T-Style)
Standard O'rings	Silicone
Capsule Body	Polypropylene
Capsule Vent Seals	Silicone
Filling Bell	Polycarbonate

11.3 Flow Characteristics

The effective filtration area of a standard 250mm (10”) module is 0.75 m^2 (7.9 ft^2).





11.4 Operating Temperatures and Pressures

Below are the recommended maximum differential operating pressures at various temperatures: -

Temperature		**Differential Pressure Cartridges**		**Operating Pressure Capsules Liquids (gases)**	
°C	°F	bar	psi	barg	psig
20	68	5.00	72.5	5.00 (4.00)	72.5 (58.0)
40	104	4.00	58.0	5.00 (4.00)	72.5 (58.0)
50	122	3.00	43.5	3.00 (3.00)	43.5 (43.5)
70	158	2.00	29.0	Not Recommended	

11.5 Steam Sterilisation

Autoclave

Product Format	**Autoclave Temp**		**Number of Cycles**	**Cycle Time (minutes at temperature)**
	°C	**°F**		
Cartridges	142	288	120	30
Capsules	135	275	10	30

To maximise cartridge and capsule life, a slow exhaust cycle is recommended.

Steam in Place (SIP)

Product Format	**SIP Temp**		**Number of Cycles**	**Cycle Time (minutes at temperature)**
	°C	**°F**		
Cartridges	142	288	120	30
Capsules	135	275	10	30

To maximise 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 **domnick hunter** guidance for the method of steam sterilisation be followed.

11.6 Tests For BioCompatibility

An independent research establishment has assessed the biological safety associated with the use of TETPOR AIR filters designed for processing pharmaceutical products. The materials used in the construction of TETPOR AIR products meet the requirements of the current USP <88> *Biological Reactivity* tests at Plastics Class VI – 121°C.

11.7 Extractables

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

Test Method (1)

Non-volatile extractables from purified water samples after flowing through an autoclaved 250mm (10") TETPOR AIR 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. S000136

Flush Quantity (litres)	Non-volatile Extract (mg per 100ml)	Oxidisables (per USP 23 Test Method)
1	0.5	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") TETPOR AIR cartridge and a B-size TETPOR AIR capsule following a 4-hour dynamic immersion in a variety of commonly used solvents. Solvent volume used 1500ml.

Solvent	Serial No. Cartridge	Weight of extract (mg)	Serial No. Capsule	Weight of extract (mg)
Water	M41711	2.2	A022783	<0.01
Iso Propyl Alcohol (IPA)	M41719	17.6	A022782	0.38
Ethanol	M41729	9.8	A022777	0.11
Methanol	M41717	12.0	A022773	3.00
Ammonium Hydroxide (pH12)	M41708	0.8	A022776	<0.01
Hydrochloric Acid (pH3)	M41714	8.3	A022774	<0.01

11.8 Integrity Testing Data

The following is the integrity test information for the micron ratings available within the TETPOR AIR product range. Diffusional flow and bubble point values are given for cartridges wetted in 60:40$_{v/v}$ IPA:Water solution.

Micron Rating	Minimum Bubble Point[8]		Diffusional Flow Test Pressure		Maximum Diffusional Flow (ml/min)				
Liquid / Gas	bar	psi	bar	psi	10"	K	A[9]	B[7]	E[7]
0.20 / 0.01	1.00	14.5	0.80	11.6	18.0	8.5	6.0	3.0	1.5
			Water Intrusion Test Pressure		Maximum Water Intrusion (ml/10min)				
			bar	psi	10"	K	A[7]	B[7]	E[7]
			2.50	36.3	16.0	7.5	5.3	2.6	1.3

12 Correlation of Non-Destructive Integrity Testing to Liquid Bacterial Challenge with *Brevundimonas diminuta* (ATCC 19146) for 0.20 µm Sterilising Grade Filters

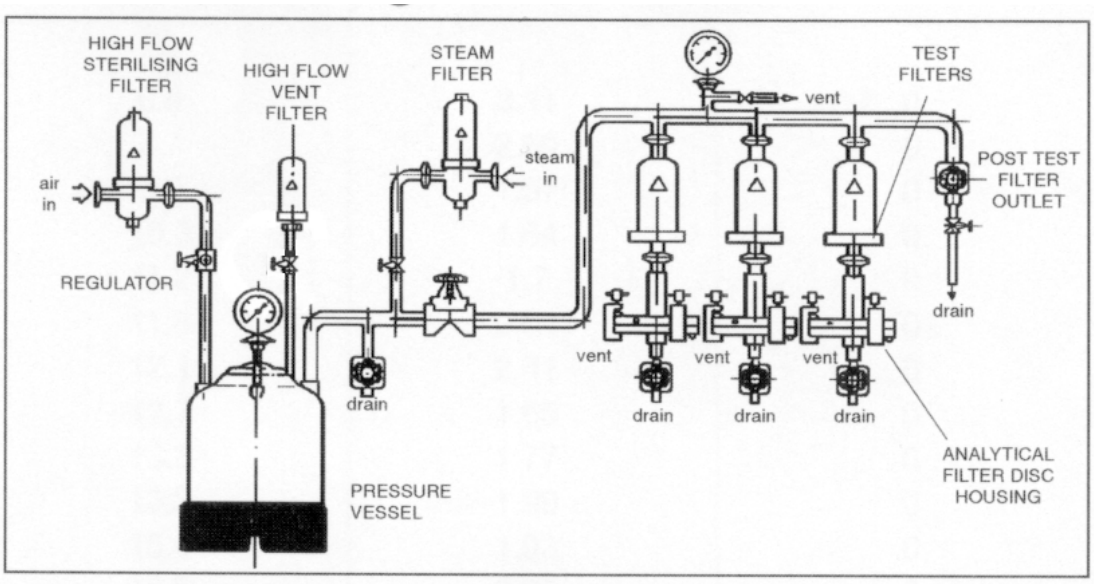
To guarantee filter performance a filter must be capable of being non-destructively integrity tested. This was recognised by the FDA in the "Guideline on Sterile Drug Products produced by Aseptic Processing" (June 1987), which states:

"After a filtration process is properly validated for a given product process and filter, it is important to assure that identical filter replacements (membrane or cartridge) used in production runs will perform in the same manner. One way of achieving this is to correlate filter performance data with filter integrity testing data. Normally, integrity testing of the filter is performed after the filter unit is assembled and sterilised prior to use. More importantly, however, such testing should be conducted after the filter is used in order to detect any filter leaks or perforations that may have occurred during the filtration."

To achieve this objective the correlation between bacterial challenge retention and a non-destructive integrity test must be proven. The procedure documented in ASTM F838-83, 'Standard Test Method for Determining Bacterial Retention Of Membrane Filters Utilized For Liquid Filtration', is used to test the manufactured product[10]. The filter must be challenged with a minimum of 10^7 viable *Brevundimonas diminuta* (ATCC 19146) per cm^2 of effective filtration area.

[8] **domnick hunter** does not recommend the use of bubble point as an integrity test method for cartridges and capsules, but values are given for use as an indicator of product integrity.
[9] DEMI Cartridge and DEMICAP Capsule.
[10] Previous reference to the guidance document *Microbial Evaluation of Filters for Sterilising Liquids*, HIMA Document No. 3 Vol. 4, April 1982, referred to in USP<1211> *Sterilisation by Filtration* has been superseded by the equivalent ASTM F838-83.

12.1 Liquid Bacterial Challenge Schematic



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 bacterial challenge is quantified by expressing the filters' efficiency to remove the challenge organism from the challenge suspension as a Log Reduction Value (LRV). To be classed as a sterilising grade filter the test filter must produce a sterile filtrate and LRV > 7.0.

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

12.2 Diffusional Flow Correlation

Table 1 lists TETPOR AIR 0.01 μm cartridges that were diffusional flow integrity tested before and after bacterial challenge. The bacterial challenge was conducted using ASTM F838-83 so providing the necessary correlation between a bacterial challenge and a non-destructive diffusional flow test.

Table 1 indicates that a 250mm (10") TETPOR AIR 0.01 μm filter exhibiting a diffusional flow of <22.0 ml/min when completely wet out in 60:40$_{v/v}$ IPA:Water, at a test pressure of 0.80 barg (11.6 psig) at 20°C (68°F) will produce a sterile filtrate. To build in an added level of security, **domnick hunter** has reduced the allowable diffusional flow.

A 250mm (10") TETPOR AIR 0.01 μm filter, that is completely wet out in 60:40$_{v/v}$ IPA:Water, has a maximum diffusional flow value of:

18.0 ml/min at a test pressure of 0.80 barg (11.6 psig) at 20°C (68°F).

The maximum diffusional flow for other TETPOR AIR filters is based upon the ratio of the surface area compared to that of a 250mm (10") cartridge.

Table 1: Diffusional Flow Correlation Data

Filter Type: ZCMT1/-020C-A TETPOR AIR 0.01μm 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[11]
M32898	0.5	1.70	0	11.23
M36067	2.0	2.50	0	11.40
M32903	2.2	1.34	0	10.64
M32914	2.2	2.64	0	10.21
M36065	2.3	0.31	0	10.49
M32894	3.1	1.64	0	11.21
M32902	3.1	1.77	0	11.25
M41707	3.5	0.14	0	10.10
M32908	3.7	2.41	0	11.38
M41710	5.1	0.15	0	10.17
M36069	6.1	1.57	0	11.20
N008205	6.6	2.88	0	11.45
M37703	6.7	3.25	0	11.51
M32916	6.7	2.32	0	11.36
M32910	6.8	1.65	0	11.22
M41722	6.8	0.13	0	10.11
N008204	7.0	1.99	0	11.30
M37700	7.2	3.08	0	11.40
J29578	7.9	1.80	0	11.18
J29577	7.9	3.02	0	11.48
S000143	9.9	2.87	0	11.46
M36064	11.0	3.11	0	11.49
M37710	11.0	2.01	0	11.30
E92447	22.0	0.52	0	10.72
M38639	22.4	3.29	15	10.30
M41723	36.5	0.40	333	7.79

[11] Where Organisms passed = 0, LRV is stated as *greater than*.

12.3 Water Intrusion Correlation

Table 2 proves the correlation that a 250mm (10") TETPOR AIR 0.01um filter with a Water Intrusion value of <20.0 ml / 10min at a test pressure of 2.50 barg (36.3 psig) at 20ºC (68ºF) will produce a sterile filtrate. To build in an added level of security, **domnick hunter** has reduced the allowable Water Intrusion value.

A 250mm (10") TETPOR AIR 0.01 um filter has a maximum allowable Water Intrusion value of:

16.0 ml / 10min at a test pressure of 2.50 barg (36.3 psig) at 20ºC (68ºF).

The Water Intrusion values for other TETPOR AIR filters are based upon the ratio of the surface area compared to that of a 250mm (10") cartridge.

Table 2: Water Intrusion Correlation Data

Filter Type: ZCMT1/020C-A TETPOR AIR 0.01μm 10" Cartridge

Challenge Organism: *Brevundimonas diminuta* (ATCC 19146)

Serial No.	WI @ 2.50 barg (36.3 psig) *ml/10min*	Challenge Level (x 10^{11})	Organisms Passed	LRV[12]
M36064	6.0	3.11	0	11.49
M36067	7.7	2.50	0	11.39
M36069	7.9	1.57	0	11.19
M32894	10.3	1.64	0	11.21
M32898	11.2	1.70	0	11.23
M32907	11.8	2.04	0	11.31
M32908	12.1	2.41	0	11.38
M32910	12.7	1.65	0	11.22
M32902	13.3	1.77	0	11.25
N008204	13.3	1.99	0	11.30
M32896	15.4	1.93	0	11.29
M32916	16.0	2.32	0	11.37
M32915	20.1	1.99	0	11.30
N008200	29.3	1.19	TNTC[13]	<7.00
M38638	38.4	1.62	2083	7.90
M38636	74.2	3.29	16	10.30

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

13 Retention to Aerosolised *Brevundimonas Diminuta*

Tests have shown that TETPOR AIR is fully retentive to aerosolised *Brevundimonas diminuta* (ATCC 19146) bacteria when challenged with a total of $2x10^9$ cfu over a 1-hr test at the rated flow of the cartridge.

14 Chemical Compatibility

Testing has been carried out that shows TETPOR AIR filters and capsules have a broad range of chemical compatibility with chemicals commonly used in the pharmaceutical industry.

14.1 Chemical Compatibility Summary Chart for Pharmaceutical Products

	ASYPOR	BIO-X II	HIGH FLOW BIO-X	HIGH FLOW BIO-X VENT AUTOCLAVE	HIGH FLOW PREPOR GF A	HIGH FLOW TETPOR	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

	ASYPOR	BIO-X II	HIGH FLOW BIO-X	HIGH FLOW BIO-X VENT AUTOCLAVE	HIGH FLOW PREPOR GFA	HIGH FLOW TETPOR	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
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 Vol	C	-	-	-	C	-	-	-	C	C	C	C	C	C	C	C	C	C
Hydrogen Peroxide 100 Vol	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
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

	ASYPOR	BIO-X II	HIGH FLOW BIO-X	HIGH FLOW BIO-X VENT AUTOCLAVE	HIGH FLOW PREPOR GFA	HIGH FLOW TETPOR	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
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

14.2 Chemical Compatibility User Instructions and Notes

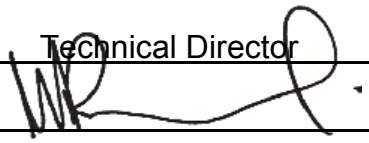
- The chemicals are arranged in alphabetical order using their most common or trade names. If the chemical in question does not appear to be listed, it may be found elsewhere in the table under a pseudonym, in particular its IUPAC[14] name.
- With regard to compatibility:
  - ◊ Any product that has Limited 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.
  - ◊ Test Conditions – 72 hrs at ambient temperature and pressure, unless otherwise stated.
  - ◊ Contact **domnick hunter** for confirmation of compatibility with specific operating conditions.

[14] IUPAC – International Union of Pure and Applied Chemistry

Documentation Approval Section

Approved By: Dr M Brailsford

Title: Technical Director

Signature: 

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