Validation Document for HIGH FLOW BIO-X Pharmaceutical Grade Cartridge 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 HIGH FLOW BIO-X surpasses the product specification requirements that have to be imposed on sterilising grade filters.

NOTE

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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 9001:2000, 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 14001:2004 for its Environmental Management System.

CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

Domnick Hunter Ltd
Birtley, Boldon, County Durham
United Kingdom

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

ISO 9001:2000

The Quality Management System is applicable to:

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

Approval Certificate No: LRQ 4000800

Original Approval: 1 October 2003
Current Certificate: 1 October 2006
Certificate Expiry: 30 September 2009

Issued by: Lloyd's Register Quality Assurance Limited

CERTIFICATE OF APPROVAL

This is to certify that the Environmental Management System of:

Domnick Hunter Ltd
Birtley, Co Durham
United Kingdom

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

ISO 14001: 2004

The Environmental Management System is applicable to:

The design, manufacture and supply of filters, fabricated housings, pipework and associated equipment for the clarification, stabilisation and sterilisation of liquids and gases. The management of the design and manufacture of electronic test equipment used to verify the integrity of filters.

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Approval Certificate No: LRQ 0773037

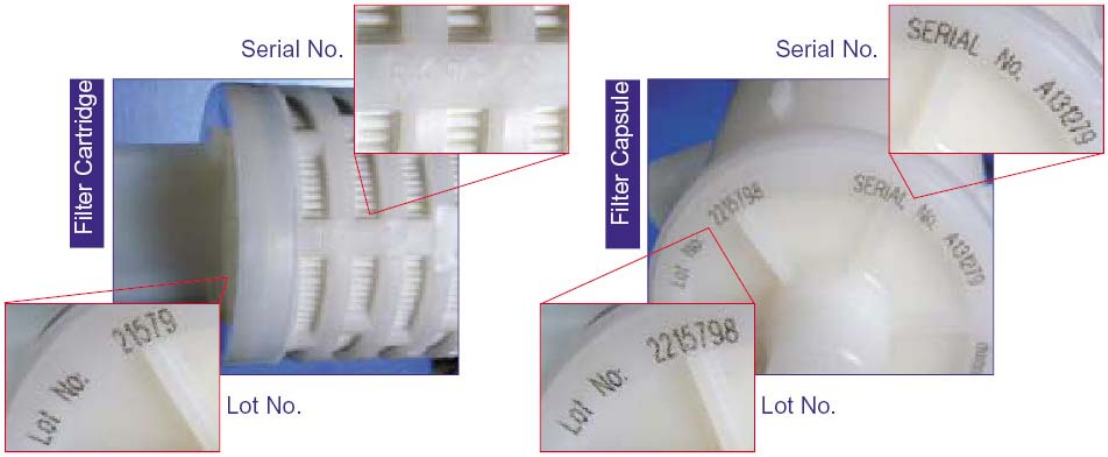
Original Approval: 6 December 2001
Current Certificate: 25 May 2005
Certificate Expiry: 31 December 2007

Issued by: Lloyd's Register Quality Assurance Limited

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.

Media Validation		**Filter Validation and Testing**				
Physical	**Chemical / Biological**	**Integrity Testing**	**Retention**	**Flow Parameters**	**Durability**	**Chemical / Biological**
Air Flow	Chemical Compatibility	Aerosol Challenge	Aerosol Bacterial Challenge	Clean Air Flow	Max Allowable Steam life	Chemical Compatibility
Thickness	Extractables		Aerosol Phage Challenge		Max continuous running Temperature	Extractables
Aerosol Integrity Test			Particle / Fibre Shedding		Max Allowable Differential Pressure	Bio-Compatibility
						Pyrogen Extractables
						Oxidisables

[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

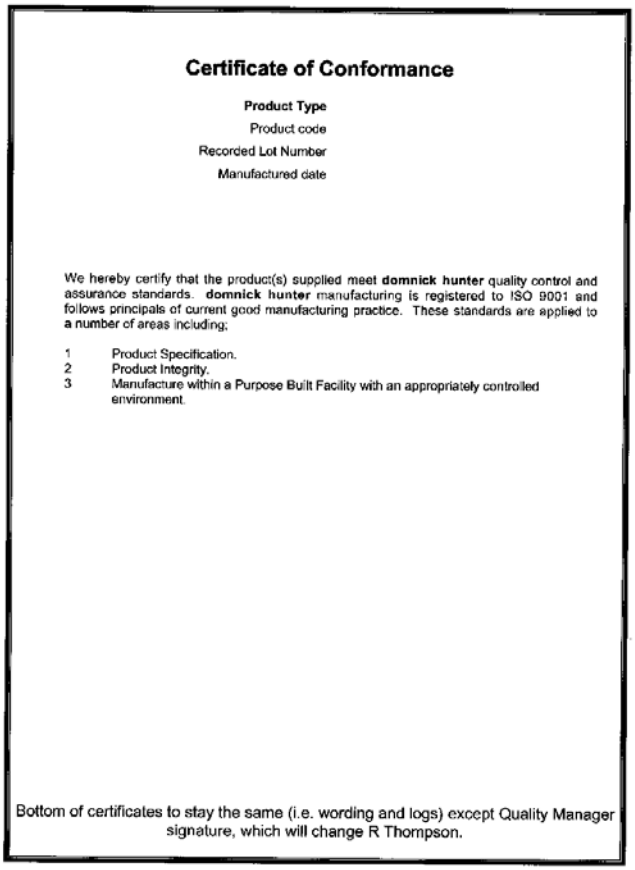
HIGH FLOW BIO-X filters must meet stringent standards to be certified P-grade product by **domnick hunter ltd**. The standards that must be met are:-

- Conformance 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).
- 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 aerosol bacterial challenge.

6 Certificate of Conformance

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

The example following is for HIGH FLOW BIO-X cartridge filters.



Certificate of Conformance

Product Type
Product code
Recorded Lot Number
Manufactured date

We hereby certify that the product(s) supplied meet **domnick hunter** quality control and assurance standards. **domnick hunter** manufacturing is registered to ISO 9001 and follows principals of current good manufacturing practice. These standards are applied to a number of areas including;

1 Product Specification.
2 Product Integrity.
3 Manufacture within a Purpose Built Facility with an appropriately controlled environment.

Bottom of certificates to stay the same (i.e. wording and logs) except Quality Manager signature, which will change R Thompson.

7 Product Coding and Range for HIGH FLOW BIO-X Cartridges

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

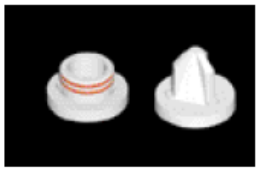
Example: ZCHB-1C 250mm (10") HIGH FLOW BIO-X filter cartridge, with 'C' style endcap and Silicone O'rings.

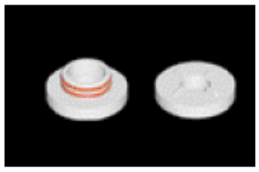
ZCHB - [ ] [ ]

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

Code	10" Endcap Style
C	P-7
P	Bio-X Retrofit
H	UF Retrofit
Code	**DEMI Endcap Style**
H	UF Retrofit
T	TRUESEAL
Y	DEMI MCY
Z	DEMI A&B Std

8 Endcap Configuration Diagrams


A Style 223 'O' Rings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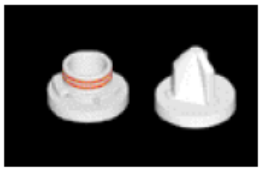
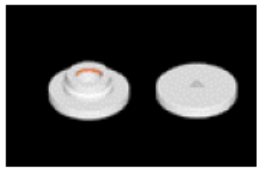
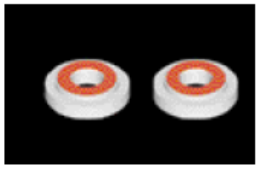
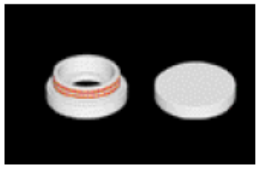
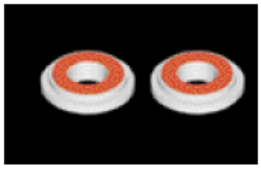
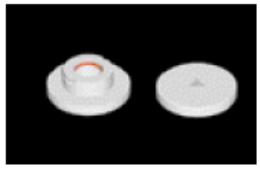

R Style 226 'O' Rings

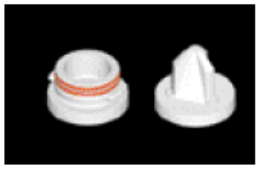

W Style 111 'O' Rings (Demi Only)


B,L Style Flat Gaskets


H Style 54mm ID x 4mm 'O' Rings


S Style Flat Gaskets


X Style 116 'O' Rings (Demi Only)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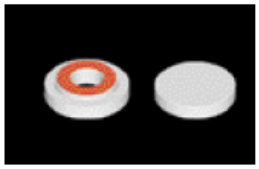
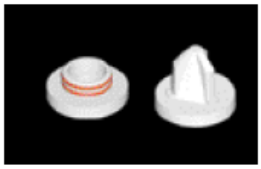
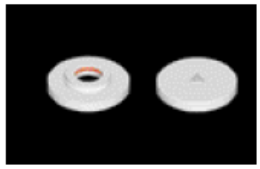
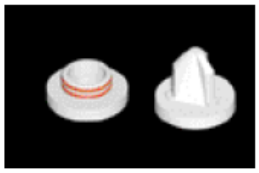
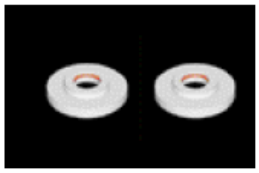
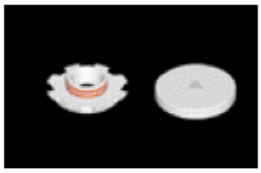

J Style S.O.E.

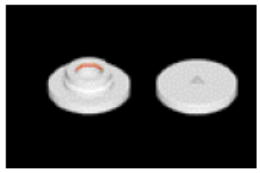

U Style 222 'O' Rings

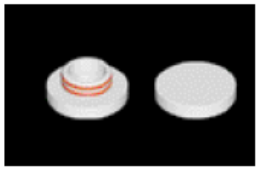

Y Style 116 'O' Rings (Internal) (Demi Only)

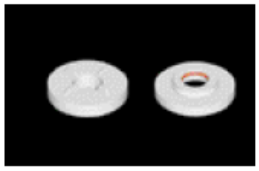

D Style 222 'O' Rings

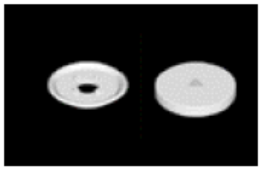

K Style 214 'O' Rings (Internal)

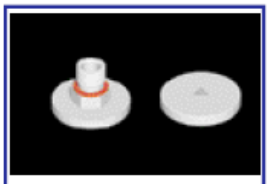

O Style 123 'O' Rings (Demi Only)

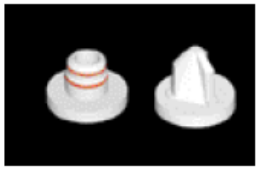

Z Style 116 'O' Rings (Internal) (Demi Only)

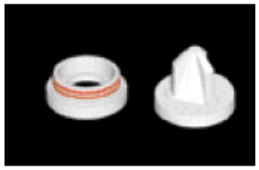

E Style 222 'O' Rings

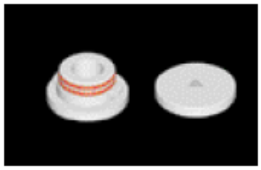

M,N Style 214/213 'O' Rings (Internal)

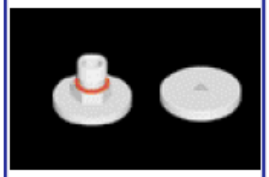

SK Style (Demi Only)


X Style 1/2" NPTM Thread & Gasket


F Style 216/218 'O' Rings


P Style 227 'O' Rings


T Style 126 'O' Rings (Demi Only)


V Style BSPP Thread & Gasket

Autoclave Vent Filter Endcaps

9 Product Specification

9.1 Application

All products within the HIGH FLOW BIO-X range have been designed for use in pharmaceutical applications for sterilisation duties, evaluated using an aerosol bacterial challenge with *Brevundimonas diminuta*.

9.2 Materials of Construction for HIGH FLOW BIO-X Cartridges and Capsules

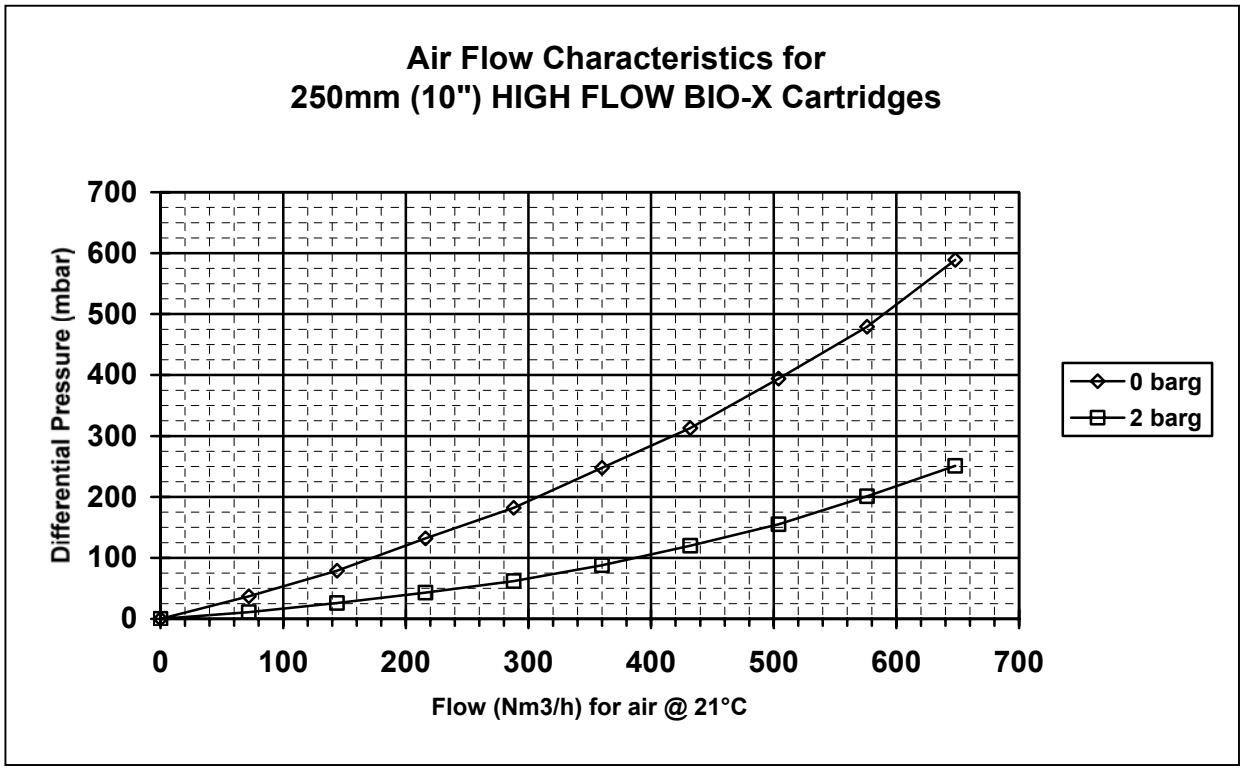
All materials used in the construction of HIGH FLOW BIO-X products that have product contact have met the requirements of the current USP Biological Reactivity Tests, In Vivo to Plastics Class VI-121°C.

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 Media	Polytetrafluoroethylene (PTFE) Impregnated Borosilicate Glass Microfibre
Upstream Support	Polypropylene
Downstream Support	Polypropylene
Inner Support Core	316 Stainless Steel
Outer Protection Cage	Polypropylene
Endcaps	Polypropylene
Endcap Insert	316 Stainless Steel
Standard O'rings	Silicone

9.3 Flow Characteristics

The effective filtration area of a standard 250mm (10”) module is 0.38 m^2 (4.3 ft^2).



9.4 Operating Temperatures and Pressures

The recommended continuous maximum differential operating pressure / temperature: -

Temperature		Differential Pressure Cartridges	
°C	°F	bar	psi
70	158	3.50	50.8

9.5 Steam Sterilisation

Autoclave

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

To maximise cartridge 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

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.

9.6 Tests For BioCompatibility

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

9.7 H_2O_2 Sterilisation

HIGH FLOW BIO-X cartridges can be repeatedly sterilised using gaseous phase H_2O_2 at concentrations up to 5 mg/litre.

9.8 Extractables

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

Test Method (1)

Non-volatile extractables from purified water samples after flowing through an autoclaved 250mm (10”) HIGH FLOW BIO-X 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. W309149

Flush Quantity (litres)	Non-volatile Extract (mg per 100ml)	Oxidisables (per USP 23 Test Method)
1	0.7	PASS
2	0.4	PASS
4	<0.1	PASS
6	0.5	PASS
8	0.5	PASS
10	<0.1	PASS

Test Method (2)

Non-volatile extractables from an autoclaved 250mm (10") HIGH FLOW BIO-X cartridge following a 4-hour dynamic immersion in a variety of commonly used solvents. Solvent volume used 1500ml. Weight of extract given as mean of three cartridges.

Solvent	Weight of extract (mg)
Water @ 20°C	20.1
Water @ 80°C	14.1
Iso Propyl Alcohol (IPA)	39.2
Ethanol	34.5

9.9 Integrity Testing Data

The following is the integrity test information for the HIGH FLOW BIO-X product range using the VAL*AIR*DATA integrity test instrument. The product range is rated at 0.01um in dry gas.

Micron Rating	Test Time using VAL*AIR*DATA (secs)					
Gas	30"	20"	10"	K	A	B
0.01	90	60	30	15	10	7

For a cartridge to be confirmed as fully integral, the VAL*AIR*DATA must display "PASS". The "PASS" value set within the instrument, is correlated to an aerosol bacterial challenge, and cannot be amended.

10 Correlation of Non-Destructive Integrity Testing to Aerosol Bacterial Challenge with *Brevundimonas diminuta* (ATCC 19146) for Sterilising Grade Gas 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:

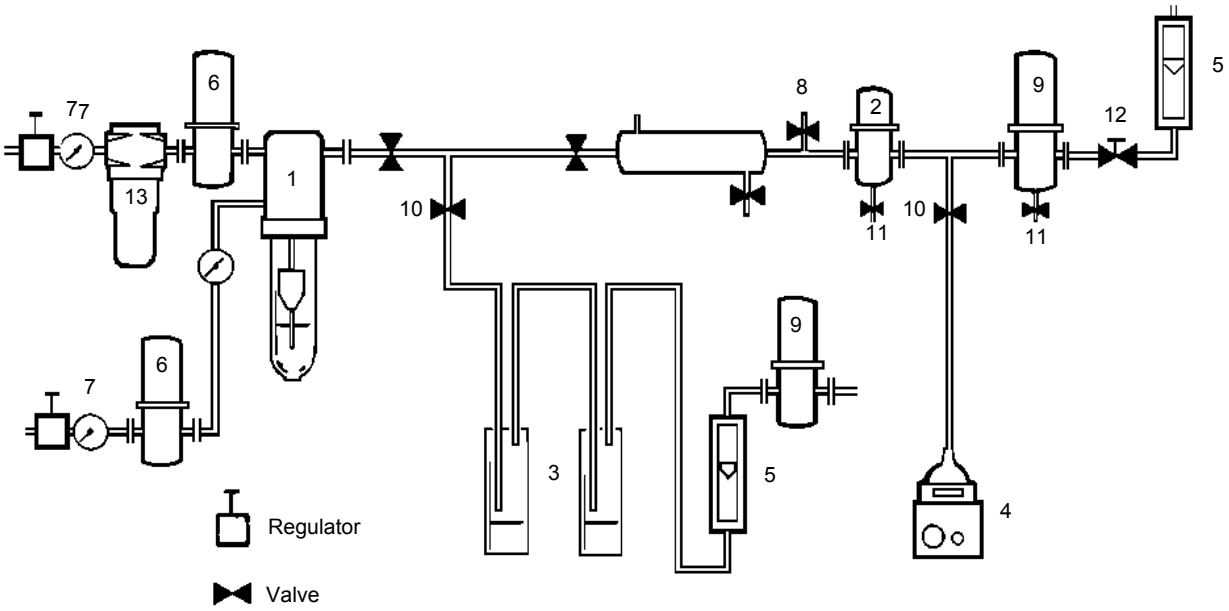
"After a filtration process is properly validated for a given product process and filter, it is important to assure that identical filter replacements (membrane or cartridge) used in production runs will perform in the same manner. One way of achieving this is to correlate filter performance data with 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. As no common procedure for aerosol bacterial challenge exists, the procedure documented in ASTM F838-83, 'Standard Test Method for Determining Bacterial Retention Of Membrane Filters Utilized For Liquid Filtration', is

adopted as a basis for the protocol used to test the manufactured product[4]. The filter must be challenged with a minimum of 10^7 viable *Brevundimonas diminuta* (ATCC 19146) per cm^2 of effective filtration area. The methodology is also referenced in "Integrity Testing Air Sterilisation Filters, A Comparison of Aerosol Challenge with Airborne Microbiological Challenge Methods, Pharmaceutical Technology Europe, April 1995"[5]

Non-destructive testing of filter integrity is carried out using a **domnick hunter** VAL*AIR*DATA integrity test Instrument with a minimum sensitivity of 0.00005%.

10.1 Aerosol Bacterial Challenge Schematic



1. Nebuliser
2. Test Filter Housing
3. Impinger Samplers
4. Slit Sampler
5. Flow Meter
6. Inlet Air Sterilising Filters
7. Pressure Regulation
8. Steam Inlet
9. Exhaust Gas Sterilising Filter
10. Sampling Port
11. Drainage Port
12. Flow Control Valve
13. Inlet Air Prefilter

[4] 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.

[5] S. Johnston, A.M. Bennett, S.R.Parks, Dr. J.E. Benbough – Biosafety Investigation Unit, Centre for Applied Micro-biology and Research, Porton Down, UK

10.2 VAL*AIR*DATA *Aerosol Correlation*

Table 1 lists HIGH FLOW BIO-X cartridges that were aerosol 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") HIGH FLOW BIO-X filter exhibiting an integrity test reading of 0.00068%, using a VAL*AIR*DATA integrity test instrument, is fully retentive to an aerosol challenge of *Brevundimonas diminuta*.

domnick hunter has applied a margin of safety and gives a PASS level based on the sensitivity of the instrument. The sensitivity of a VALAIRDATA Integrity Test Instrument is 0.00005%.

> **Any filter when tested for integrity that gives a PASS reading using the VAL*AIR*DATA, i.e. 0.00005% or less, is therefore validated as fully retentive to aerosol bacterial challenge.**

Table 1: Aerosol Challenge Correlation Data

Filter Type: ZCHB-1C HIGH FLOW BIO-X 10" Cartridge

Challenge Organism: *Brevundimonas diminuta* (ATCC 19146)

Serial No.	cfu / litre ($x10^2$)	Total Challenge Level ($x10^{10}$)	Slit Samples		LRV[6]	Aerosol Penetration VAL*AIR*DATA (%)
			Initial	Final		
143309	19300	3.53	0	0	10.55	<0.00005
132777	20200	3.64	0	0	10.56	<0.00005
143253	37600	7.33	0	0	10.87	<0.00005
143061	13900	2.51	0	0	10.40	<0.00005
143037	10700	1.76	0	0	10.24	<0.00005
143243	4400	0.80	0	0	9.90	<0.00005
143286	535	0.0963	0	0	8.98	0.00011
143337	9.35	0.00168	0	0	7.23	0.00014
132784	12.3	0.00222	0	0	7.35	0.00024
143182	32400	5.34	0	0	10.72	0.00068
143268	606	0.109	21	5	7.62	>0.01
142985	275	0.0494	41	65	6.67	>0.01

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

11 Chemical Compatibility

Testing has been carried out that shows HIGH FLOW BIO-X filters have a broad range of chemical compatibility with chemicals commonly used in the pharmaceutical industry.

11.1 Chemical Compatibility Summary Chart for Pharmaceutical Products

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

11.2 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[7] 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.

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

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