Validation Document for PEPLYN PLUS Pharmaceutical Grade Cartridge and DEMICAP Capsule Filters

domnick hunter

PROCESS FILTRATION

Contents

1 Introduction

Clarification or pre-filters that come into contact with pharmaceutical products, such as injectable or infusion liquids, 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 pharmaceutical 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 PEPLYN PLUS surpasses the product specification requirements that have to be imposed on pharmaceutical grade filters.

NOTE

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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 Policy

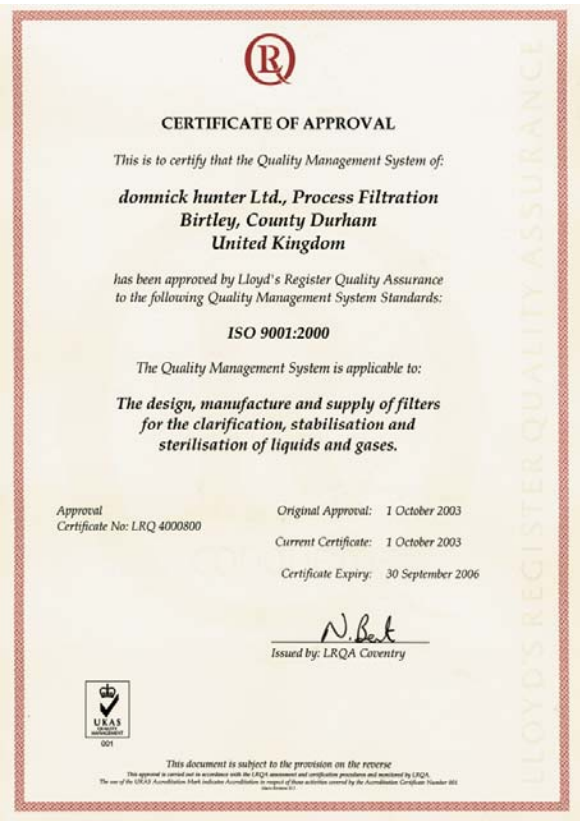
2.1 Quality Assurance

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 14001:1996 for its Environmental Management System.



CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

domnick hunter Ltd., Process Filtration
Birtley, 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:

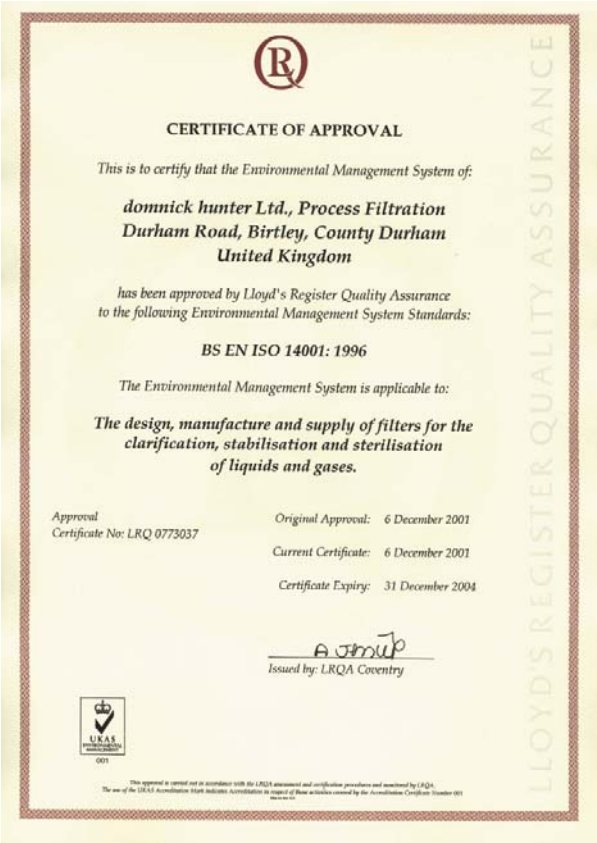
The design, manufacture and supply of filters for the clarification, stabilisation and sterilisation of liquids and gases.

Approval Certificate No: LRQ 4000800

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

Issued by: LRQA Coventry

This document is subject to the provision on the reverse



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.

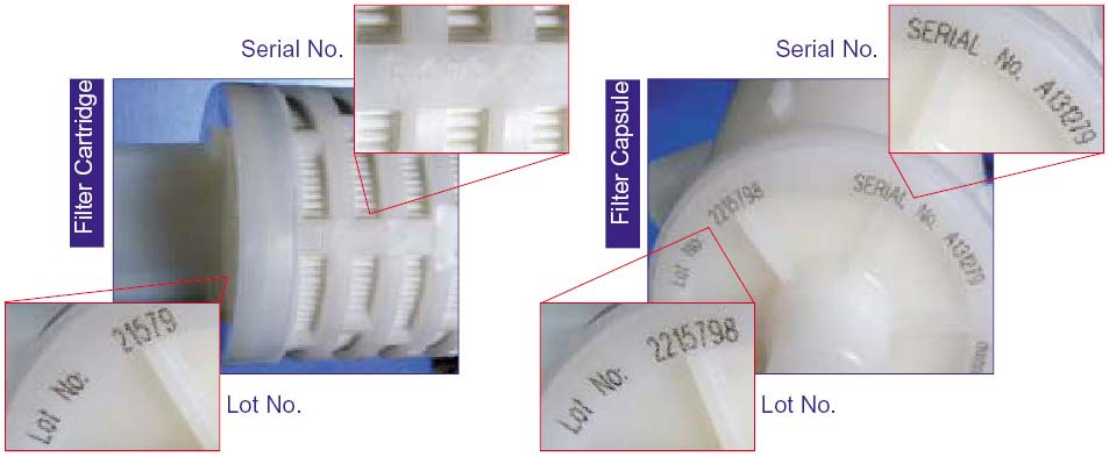
Approval Certificate No: LRQ 0773037

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

Issued by: LRQA Coventry

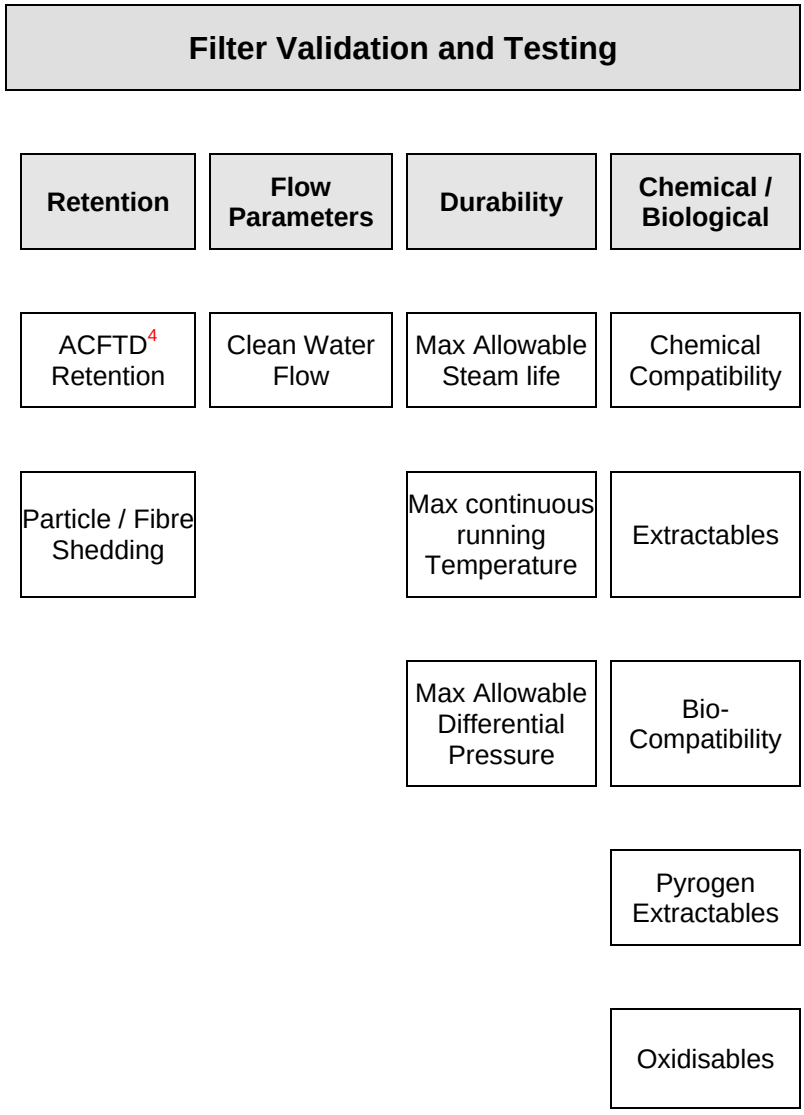
3 Product Traceability

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.



[2] ISO – International Organisation for Standardisation
[3] ASTM – American Society for Testing and Materials
[4] ACFTD – AC Fine Test Dust

5 Preparation of Pharmaceutical Grade Filters

5.1 Pharmaceutical Grade Standard

PEPLYN PLUS 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).
- 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 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** PEPLYN PLUS filter products meet the highest pharmaceutical quality and performance requirements, a Certificate of Conformance is issued.

The example following is for PEPLYN PLUS cartridge filters.[5]

Certificate of Conformance

For Pharmaceutical Grade **PEPLYN PLUS PreFilters**
Rated To 20.00 Micron(s)
This certifies that the **domnick hunter** *filter* ZCPP1-020C
Recorded Lot Number SAMPLE

has been manufactured in a purpose built facility within a controlled environment and where applicable 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.

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 0.125 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 (Sterilisable Grades)
Integrity was maintained after steam cycles of minutes at °C

This Product is registered with the Food & Drug Administration
Drug Master File No 7564

Quality Manager
28/05/02

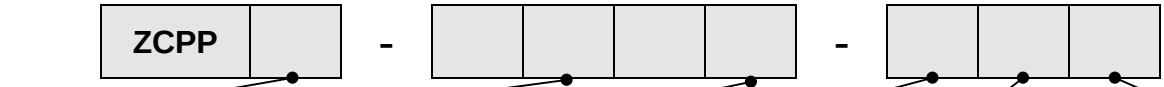
domnick hunter limited - Process Filtration,Durham Road,Birtley,Co.Durham,England DH3 2SF
Tel: +44 (0) 191 4105121 Fax: +44 (0) 191 4105312

[5] A specific Certificate of Conformance is issued for DEMICAP capsules.

7 Product Coding and Range for Cartridges

Represented below are details of the product code structure for PEPLYN PLUS cartridges. This product code structure indicates cartridge sizes, micron ratings, end-cap configurations and 'O' ring materials that are available within the product range.

Example: **ZCPP2-010C-P** - 500mm (20") 10.0 micron PEPLYN PLUS filter, Pharmaceutical Grade with 'C' style end-cap and silicone O' rings.



Code	mm	Inch
B	65	2.5
A	125	5
K	125	5
1	250	10
2	500	20
3	750	30
4	1000	40

Code	Micron Rating	Code	Micron Rating
.60	0.6	015	15.0
1.0	1.0	020	20.0
1.5	1.5	025	25.0
003	3.0	040	40.0
005	5.0	055	55.0
007	7.0	075	75.0
010	10.0	100	100.0

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
P	Pharmaceutical

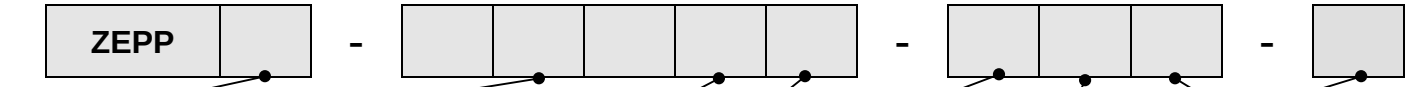
Code	O' rings[6]
E	EPDM[7]
P	FEP Encapsulated Silicone
V	Viton[8]
S	Silicone

Code	Additional Spec

8 Product Coding and Range for Capsules

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

Example: **ZEPPB-010TT-PN3** - B-size 10.0 micron PEPLYN PLUS Capsule, Pharmaceutical Grade with a Tri-Clamp inlet and outlet connection, non-sterile in packs of 3.



Code	Dimensions
E	See diagrams Section 10
B	
A	

Code	Micron Rating	Code	Micron Rating
.60	0.6	015	15.0
1.0	1.0	020	20.0
1.5	1.5	025	25.0
003	3.0	040	40.0
005	5.0	055	55.0
007	7.0	075	75.0
010	10.0	100	100.0

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 6 -12mm Hosebarb	Stepped 6 -12mm Hosebarb
M	¼" NPT Male	¼" NPT Male
S	-	Showerhead
R	Grommel QRC Male	-
Q	Walther QRC Male	-

Code	Variant
P	Pharmaceutical

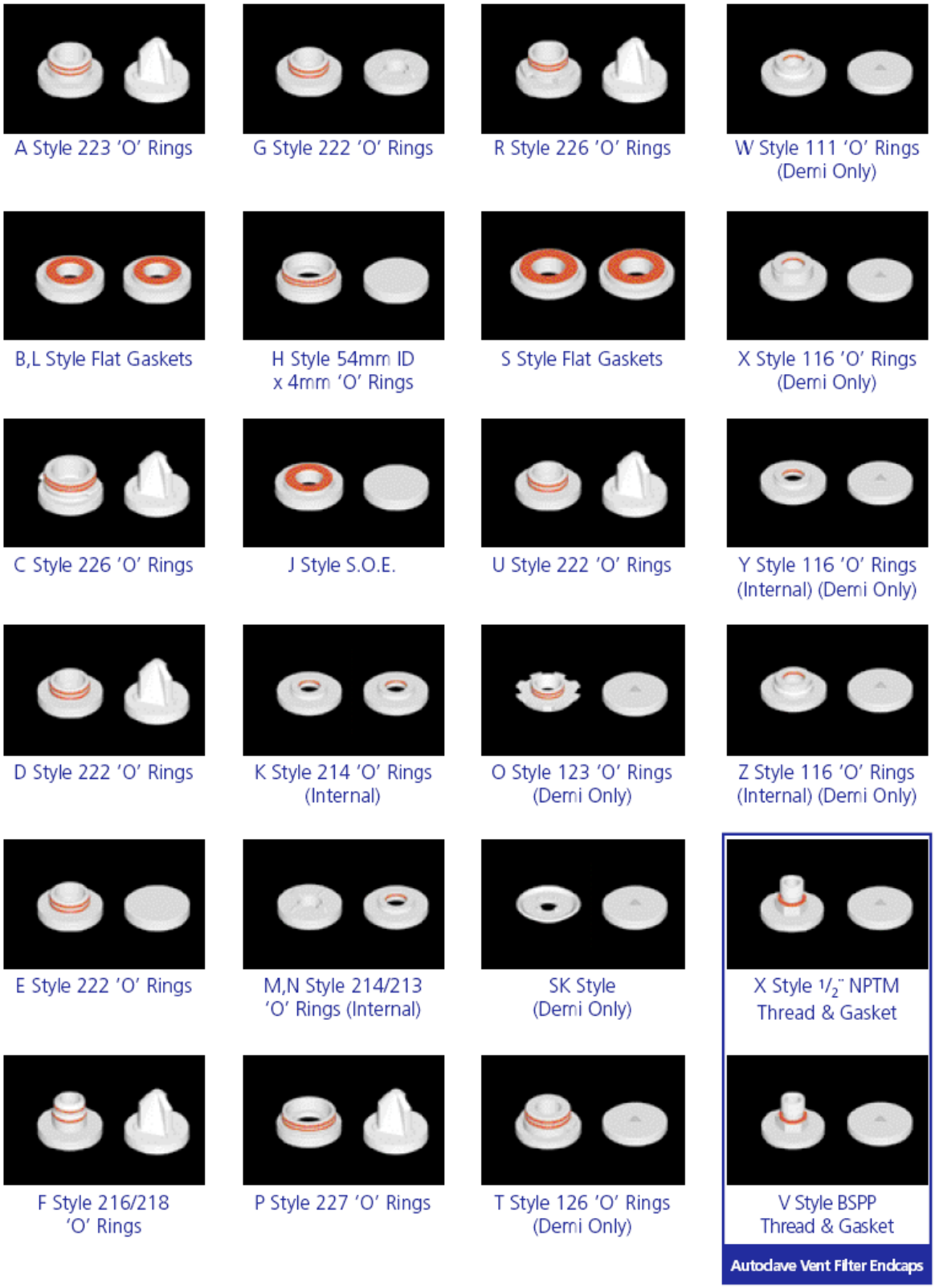
Code	Grade
N	Supplied Non-sterile
S	Supplied Gamma Pre-sterilised

Code	Additional Specification
3	3 per pack

Code	Additional Specification
FB	with filling bell
Available only with G and H outlet connections	

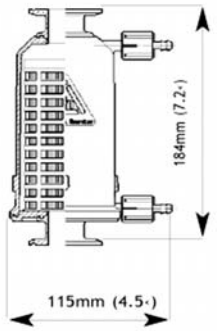
[6] Silicone O'rings are fitted as standard without having to specify the S in the code.
[7] **EPDM** – Ethylene Propylene Diene Monomer Rubber
[8] **Viton** is a registered trademark of DuPont Dow Corporation

9 Endcap Configuration Diagrams

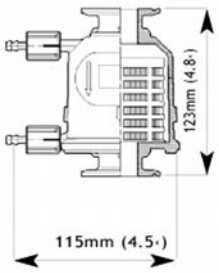


10 Capsule Dimensions

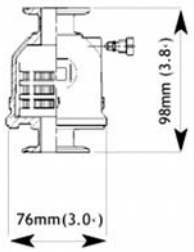
A Size



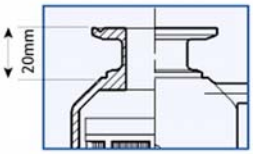
B Size



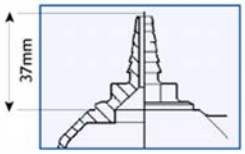
E Size



Fitted with 1" Tri-Clamp connections. Use drawings below to calculate dimensions with different configurations

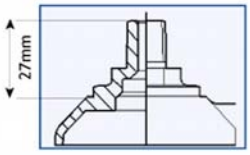


1" Tri-Clamp



Stepped Hosebarb

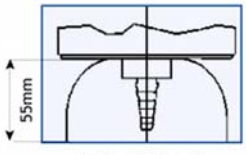
Suitable for tubing with 6mm (1/4") - 12mm (1/2") internal diameter



1/4" NPTM Thread

1/2" Hosebarb

1/2" NPTM Thread



Filling Bell with Stepped Hosebarb

NB. All dimensions nominal

11 Product Specification

11.1 Application

All products within the PEPLYN PLUS range, cartridge, capsule and disc have been designed for use in pharmaceutical applications for prefiltration and clarification duties.

11.2 Materials of Construction for PEPLYN PLUS Cartridges and Capsules

All materials used in the construction of PEPLYN PLUS 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.

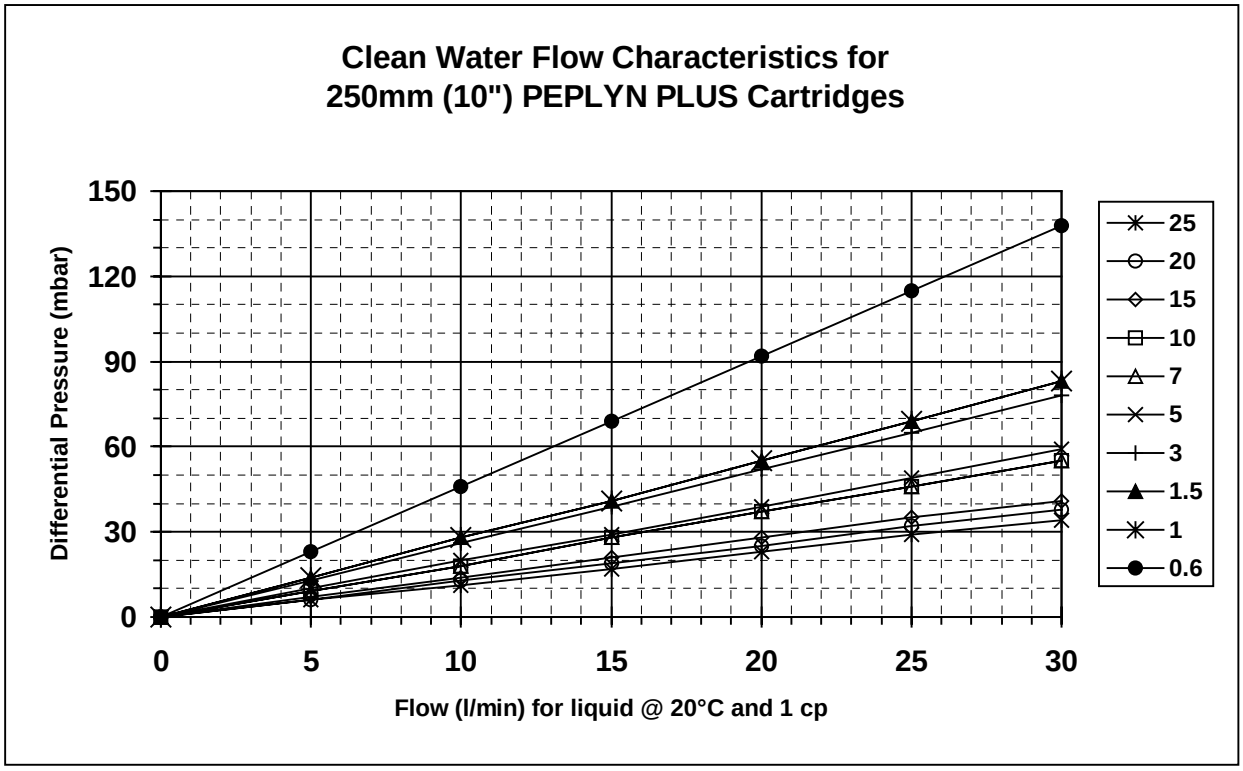
Component	Material of Construction
Filtration Media	Polypropylene
Upstream Support	Polypropylene
Downstream Support	Polypropylene
Inner Support Core	Polypropylene
Outer Protection Cage	Polypropylene
Endcaps	Polypropylene
Endcap Insert	316 Stainless Steel
Standard O'rings	Silicone
Capsule Body	Polypropylene
Capsule Vent Seals	Silicone
Filling Bell	Polycarbonate

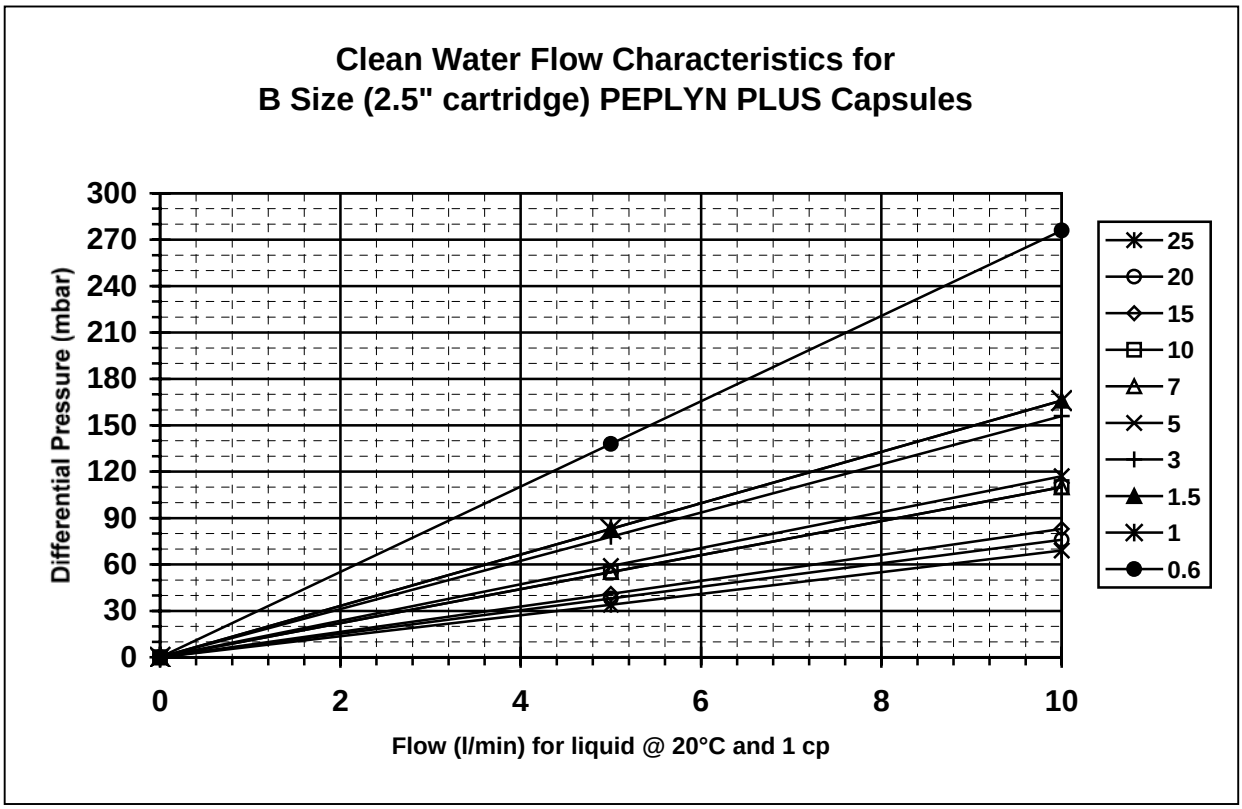
11.3 Filter Media

The high efficiency of each PEPLYN PLUS filter cartridge and DEMICAP capsule is achieved by bringing together different grades of filter media in a layered composite structure. A graded depth of filtration gives the extended life of PEPLYN PLUS from coarse particulate prefiltration to very fine ultimate retention at the filters quoted micron rating. High dirt holding capacity therefore results from the depth of filtration within each composite layer.

11.4 Flow Characteristics

The effective filtration area of a standard 250mm (10") module is upto 0.57 m^2 (6.4 ft^2), dependant on the grade selected.





11.5 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	

11.6 Steam Sterilisation

Autoclave

Product Format	**Autoclave Temp**		**Number of Cycles**	**Cycle Time (minutes at temperature)**
	°C	**°F**		
Cartridges	135	288	30	30
Capsules	135	288	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	135	288	30	30
Capsules	**Do not Steam in Place**			

To maximise the life of the cartridge, the differential pressure across the cartridge should not exceed 0.30 bar (4.4 psi) at 135°C (288°F). For new applications it is recommended that **domnick hunter** guidance for the method of steam sterilisation be followed.

11.7 Tests For BioCompatibility

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

12 Determination of Micron Ratings

Particle removal efficiencies of PEPLYN PLUS filter cartridges have been determined by challenging with a standard aqueous suspension of ACFTD (AC Fine Test Dust) with particle size as defined in table 2, using in-line laser particle counters. Testing is in accordance with ASTM F795-88 *Standard Practice for Determining the Performance of the Filter Medium Employing a Single-Pass, Constant-Rate, Liquid Test*.

Media Code		Micron Rating at Various Efficiencies				
	Efficiency %[9]	>99.99	99.98	99.90	99.0	90.0
	Beta Ratio[10]	10000	5000	1000	100	10
.60		0.60	0.57	0.54	0.32	0.20
1.0		1.00	0.95	0.90	0.70	0.50
1.5		1.50	1.40	1.10	0.80	0.60
003		3.00	2.80	1.80	1.00	0.70
005		5.00	4.70	4.50	3.50	1.00
007		7.00	6.70	6.30	4.50	2.50
010		10.00	8.00	7.00	4.80	2.80
015		15.00	12.00	10.00	7.20	4.50
020		20.00	16.00	14.00	10.00	6.00
025		25.00	20.00	17.00	12.00	7.00

Table 1: The Retention Characteristics of PEPLYN PLUS Filters

Particle Size (um)	Volume % Smaller Than	Approximate number of particles per gram in band
1	2.5 – 3.5	5×10^{10}
2	10.5 – 12.5	3×10^{10}
3	18.5 – 22.0	1×10^{10}
4	25.5 – 29.5	4×10^{9}
5	31.0 – 36.0	1×10^{9}
7	41.0 – 46.0	8×10^{8}
10	50.0 – 54.0	1×10^{8}
20	70.0 – 74.0	4×10^{7}
40	88.0 – 91.0	4×10^{6}
80	95.5 – 100	7×10^{6}

Table 2: ACFTD Specification (SAE J 726 Fine ISO 12103 Pt 1 A2 Fine) s.g. 2.6 – 2.7 g/cm^3

[9] Efficiency @ Xμm = 1- (Number of Particles in Filtrate $_{(\geq X\mu m)}$ / Number of Particles in Challenge $_{(\geq X\mu m)}$)
[10] β Ratio @ Xμm = Number of Particles in Challenge $_{(\geq X\mu m)}$ / Number of Particles in Filtrate $_{(\geq X\mu m)}$)

13 Chemical Compatibility

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

13.1 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 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

13.2 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[11] 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.

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

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