

**Quality Assurance
Procedure for
PEPLYN PLUS and
PEPLYN AIR
Cartridge Filters**



domnick hunter

PROCESS FILTRATION

Contents

PAGE NO.

1	INTRODUCTION
2	QUALITY POLICY <ul style="list-style-type: none">- Quality Assurance- Product Traceability
3	PRODUCT CODE STRUCTURE AND RANGE
3	PRODUCT SPECIFICATION
4	PREPARATION OF PHARMACEUTICAL GRADE CARTRIDGES
5	FILTER MEDIA AND CARTRIDGE QUALITY CONTROL
5	DETERMINATION OF MICRON RATINGS
6	CHEMICAL COMPATIBILITY
7	CERTIFICATE OF REGISTRATION BS EN ISO 9001 : 1994

Introduction

This document details the Quality Assurance procedures for **domnick hunter limited** pharmaceutical grade PEPLYN PLUS filter cartridgs.

The filter media is constructed from a heat bonded monofilament of inert polypropylene formed into a non-woven layer. Multiple layers are combined to produce a medium of optimum performance. PEPLYN PLUS has a dimensionally stable filter medium, it does not rely on adhesives or binders to hold the material together. Filtration takes place within the structure by the effective utilisation of recognised mechanisms of particle retention. Particles removed from the liquid are held in the matrix and are not caused to be released by system flow surges. The voids volume of PEPLYN PLUS combined with an advanced cartridge construction results in a filter capable of holding high concentrations of particles ensuring extended service life and reduced filtration costs.

NOTE

This Quality Assurance Procedure is not a controlled document unless it has a registered number and is signed and stamped by domnick hunter. If you wish to receive a registered copy and any updates automatically, then please contact the department below or fax this page with your details to:-

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Quality Policy

Quality Assurance

Quality is of paramount importance to **domnick hunter limited**. The filter cartridges are manufactured under controlled environmental conditions to the highest quality regimes and are subjected to a demanding programme of Quality Assurance. Inspection and test protocols are implemented from vendor assessment, specification and receipt of raw materials, through every stage of the manufacturing procedure culminating in a non-destructive integrity test on the filter cartridge 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 their site at Birtley, UK through to the world-wide network of filter and separation specialists.

The Quality Assurance Department liaises 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.

Product Traceability

A number of the critical procedures used within this validation guide are based on external methods sourced from publications issued by the USP, EP, FDA, ISO and ASTM*. 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.

Every filter cartridge module has a serial number stamped on the outer cage. To enable full traceability of all pharmaceutical grade filter cartridges, each cartridge module is stamped with an individual serial number and each cartridge is identified by a lot number, product code and general description shown on both the protective polyethylene bag in which the filter cartridge is sealed and also on the outer surface of the final product packaging.

All microporous filter cartridges and capsules are flushed with pharmaceutical grade water and non-destructively integrity tested. They are then dried using HEPA filtered air and then vacuum sealed in a protective polyethylene bag under clean room conditions within the production area prior to despatch.

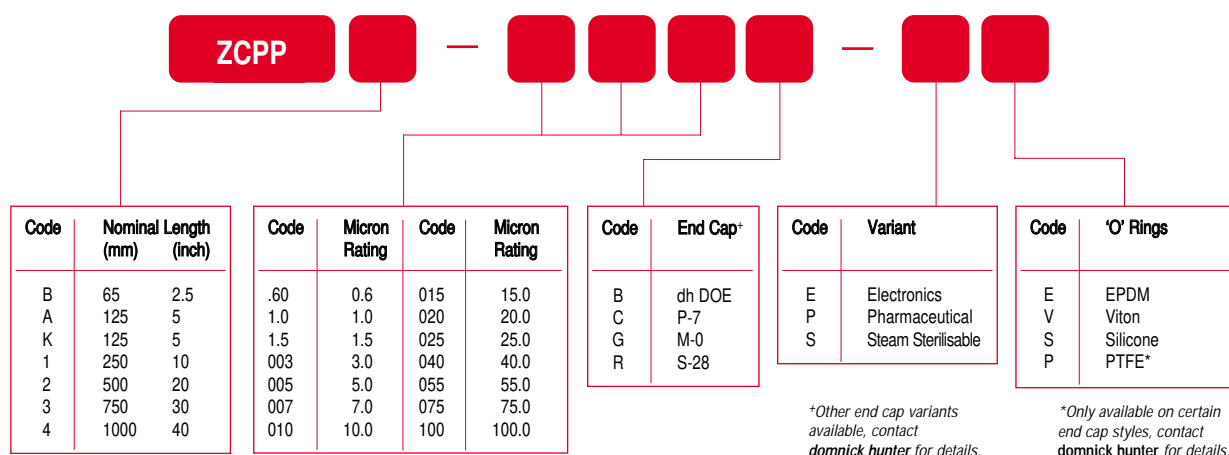
*USP (United States Pharmacopoeia), EP (European Pharmacopoeia), FDA (Food & Drug Administration), ASTM (American Society for Testing and Materials), ISO (International Organisation for Standardisation).

Product Code Structure and Range

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' rings that are available within the product range.

Examples:

ZCPP1-.60C-SS is a PEPLYN PLUS filter cartridge, 250mm in length, 0.6 micron rating with a 'C' style end cap, steam sterilisable with silicone 'O' Rings.



Product Specification

Application

All products within the product range have been designed for utilisation for the clarification and pre-filtration of a wide range of products in the pharmaceutical, beverage, ultrapure water and other critical industries. All products achieve their designated rating by a combination of direct interception, inertial impaction and diffusion.

Materials of Construction

All materials used in the construction of PEPLYN PLUS have met the requirements of the current USP Plastics Class VI - 121°C.

COMPONENT

Media
Upstream Support
Downstream Support
Core
Sleeve
End Caps

MATERIAL

Melt blown polypropylene
Polypropylene
Polypropylene
Polypropylene
Polypropylene
Polypropylene

All jointed surfaces are assembled by the use of heat sealing technology. No resins or binders are used in the manufacture of the cartridge.

Preparation of Pharmaceutical Grade Cartridges

Pharmaceutical Grade Standard

PEPLYN PLUS filter cartridges and capsules must meet stringent standards to be certified P-grade product by **domnick hunter**. The standards that must be met are:-

1. Conform with 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).
2. Effluent quality must also be met as determined by the following tests:-
 - test for oxidisable material per current USP
 - test for Bacterial Endotoxins using a gel clot Limulus Amoebocyte Lysate (LAL) test per current USP
 - test for particulates per current USP
 - test for TOC per current USP
 - test by conductivity measurement for ionic species per current USP
3. All components conform to the Biological Safety Standards as laid down in the current USP Plastics Class VI - 121°C.
4. Where specified filter cartridges and capsules can be flushed with a high flux of purified water prior to despatch as a final guarantee of product cleanliness.

Filter Media and Cartridge Quality Control

The high efficiency of each PEPLYN PLUS filter cartridge is achieved by bringing together different grades of filter media in a layered composite structure. The extended life of PEPLYN PLUS is given by a graded depth of filtration 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.

The media are subjected to a stringent 100% inspection procedure during processing. Subsequent sample tests are carried out on rolls of media and after satisfactorily meeting quality specifications, the media are built into pleated cartridge configurations.

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) using in line laser particle counters.

Table 1 The Retention Characteristics of PEPLYN PLUS filters

Media Code	Micron Rating at Various Efficiencies				
	>99.99%	99.98%	99.90%	99%	90%
.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

Chemical Compatibility

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

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 name.
- With regard to compatibility:
 - any product which has limited compatibility at 40°C should not be used at a higher temperature
 - if a filter is compatible with a refluxing chemical then it may be used at lower temperatures too, with the exception of (c) below
 - the list of compatibilities does not take into consideration any synergistic effects of more than one chemical present in the solution to be filtered.
- Key to Compatibility Chart:


C	=	Compatible
NC	=	Not Compatible
LC	=	Limited Compatibility
-	=	Not Tested

'O' Rings: E = EPR
V = Viton
S = Silicone
- Test time 72 hours at ambient temperature and pressure.

CHEMICAL	PEPLYN PLUS CARTRIDGE	'O' RINGS		
		E	V	S
Acetic acid 3.5N	C	C	C	C
Acetic acid 8.75N	C	LC	LC	NC
Acetic acid conc. 17.5N	C	LC	NC	NC
Acetone	C	NC	NC	NC
Acetonitrile	C	NC	NC	NC
Acidbrite 4 (Diversey) 3.0% v/v	C	C	C	C
Ammonium Hydroxide 8N	C	C	C	C
Ammonium Oxalate 0.07N	C	C	C	C
Amyl acetate	C	NC	NC	LC
Aqueous Ammonia 15.5N	C	C	C	C
Benzyl Alcohol	NC	C	C	C
Benzylalkonium chloride 0.1%	C	C	C	C
Boric acid, saturated	C	C	C	C
Butan-1-ol	C	C	C	C
Butan-2-ol	C	LC	C	C
Carbon tetrachloride	NC	NC	C	NC
Chloroform	NC	NC	LC	NC
Cyclohexane	NC	NC	NC	NC
1,4 - Dioxane	C	NC	NC	NC
Diverflow (Diversey) 3% v/v	C	C	C	LC
Diversey 212G 0.6% v/v	C	C	C	C
Divosan Forte 0.5% v/v	C	C	C	C
Divosan XT 1% v/v	C	C	C	C
Ethanol	C	C	C	LC
Ethanol 45%	C	C	C	C
Ethyl acetate	LC	C	NC	LC
Formaldehyde 0.3%	C	C	C	C
Formaldehyde 37%	C	C	C	C
Formic acid conc.	C	C	NC	NC
Glycerol	C	C	C	C
Hexane	NC	NC	NC	NC
Hydrochloric acid 1N	C	C	C	C
Hydrochloric acid 10%	-	-	-	-
Hydrochloric acid conc.	C	NC	NC	NC
Hydrochloric acid conc. 13%	-	NC	NC	NC
Hydrogen peroxide	C	C	C	C
Hydrogen peroxide 10 Vol	C	C	C	C
Hydrogen peroxide 100 Vol	C	C	C	C
Methanol	C	C	NC	C
Methyl-Iso-Butylketone	C	NC	NC	LC
Methylene Chloride @ 40°C	LC	-	-	-
Nitric acid 2N 14.4%	C	LC	C	C
Nitric acid 15.8N	C	NC	NC	NC
Ozone	-	-	-	-
Paraffin yellow	C	NC	C	NC
Pentane	LC	NC	C	NC
Peracetic acid 0.5% (10 week test)	-	C	C	C
Peracetic acid 4%	C	C	C	C
Perchloroethylene	-	-	-	-
Petroleum spirits	NC	NC	C	NC
Phenol (AQ) (0.5N)	-	-	-	-
Phenol 5%	C	C	C	C
Phenol 0.25%	C	C	C	C
Polyethylene Glycol 600	LC	-	-	-
Polyglycol 2000-E	-	C	C	C
Potassium dichromate 0.1N	C	C	C	C
Potassium Iodine 0.6N	C	C	C	C
Potassium hydroxide 10N	C	C	C	C
Potassium permanganate 0.1N	C	C	C	C
Propan-1-ol	C	C	C	LC
Propan-2-ol	C	C	C	LC
Propan-2-ol, 60:40 H ₂ O	C	C	C	C
Pyridine	C	C	NC	C
Sodium chloride 0.5N	C	C	C	C
Saline Lactose Broth	C	C	C	C
Sodium hydroxide 2N,8%	C	C	C	C
Sodium hydroxide 7N,28%	C	C	C	LC
Sodium hypochlorite	-	-	-	-
Sodium hypochlorite (14% Free CL ₂)	C	C	C	C
Sodium salts	-	-	-	-
Sodium thiosulphate 0.1N	C	C	C	C
Sulphuric acid 1N	C	C	C	C
Sulphuric acid conc.	LC	-	-	-
Sulphurous acid	-	-	-	-
Toluene	NC	NC	LC	NC
1,1,1 Trichloroethane	-	-	-	-
1,1,2 Trichloroethane	LC	NC	LC	LC
Trichloroacetic Acid 80%	C	NC	LC	NC
Trichloroacetic Acid 5N	-	-	-	-
Toluene	-	NC	LC	NC
Xylene	NC	C	LC	NC

Certificate of Registration BS EN ISO 9001 : 1998


Certificate of Registration



Certificate Number FM 39187

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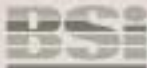


Signed on behalf of BSI, N Overton, General Manager


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