

Zetapor SP® 0.45µm Pharmaceutical Grade Cartridge



The Zetapor® SP 0.45 µm pharmaceutical grade filter cartridges provide safe, reliable, and efficient operation. The Zetapor SP 045 has been validated for bacteria removal, and has passed the USP XXI Class VI Safety Test. The electropositive charge of the Zetapor membrane offers highly efficient filtration where removal to 0.45 µm is required. Because most particles are negatively charged, the positive charge throughout the Zetapor membrane matrix captures particles smaller than the rated pore size through electrokinetic adsorption.

APPLICATIONS

- ◆ Large Volume Parenterals - Final Filtration
- ◆ Pre-Filtration of Serums, Tissue Cultures, and Growth Media
- ◆ Final Filtration of Diagnostic Reagents

PERFORMANCE

The Zetapor SP 045 filter has passed a validation test program that documents product claims and safety. The sections that follow detail the extent of the testing.

Bacterial Removal

Bacterial removal to levels in excess of 10^6 cells/cm² was verified using ASTM challenge procedures with *Serratia marcescens* as the test organism.

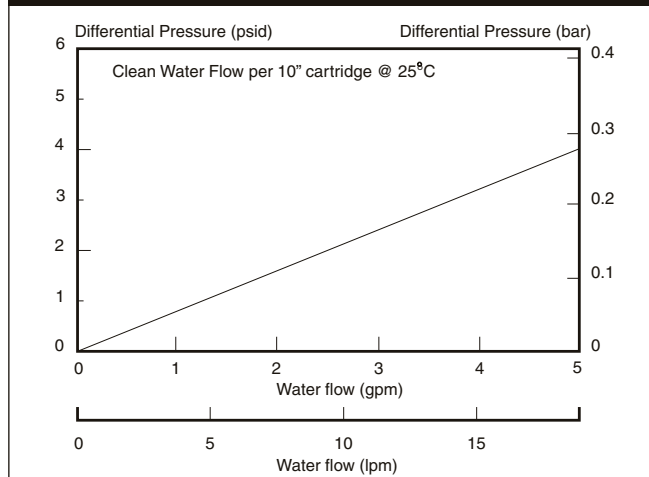
Integrity Test

The Integrity Tests document the relationships between 100% bacteria retention and two non-destructive integrity tests.

Flow Rates

The Zetapor SP 045 filter provides consistent water flow rates. The average data from the water flow analysis is represented by the solid line on Graph 1.

GRAPH 1. - WATER FLOW RATE AT 25°C



Sterilization

The Zetapor SP 045 cartridge can be sterilized by *in situ* steam or autoclaved for up to 10 hours at 293°F (145°C).

FEATURE

- Electropositive charge on Nylon 66 membrane
- 100% Integrity tested before shipment

BENEFIT

- Enhanced particle removal & pyrogenic reduction
- Reliable and consistent cartridge integrity

Biological Safety

The Zetapor SP 0.45 µm cartridge is biologically safe as determined by the USP XXI Class VI Safety Test for Plastics. The complete Biological Safety Test Report is available upon request.

Quality Assurance

Zetapor SP 0.45 cartridges are 100% integrity tested, by the diffusion flow method, prior to shipment. Each cartridge lot is sample tested for pyrogenicity, bacteria retention, total extractables, and oxidizable substances. Each cartridge is engraved with a unique serial number to ensure traceability from raw materials through the finished product.

EXTRACTABLES

Oxidizable Substances and Pyrogenicity

The Zetapor SP 0.45 µm cartridge is low in extractable oxidizable substances and is non-pyrogenic. However, it is recommended, as a good manufacturing practice, to rinse the cartridge with 1000 ml of fluid (WFI or product per 10 inch element) prior to use.

Gravimetric Extractables

The Zetapor SP 0.45 µm cartridge was tested for total gravimetric extractables by a 4-hour soak test. Extractable values are contained in the validation guide.

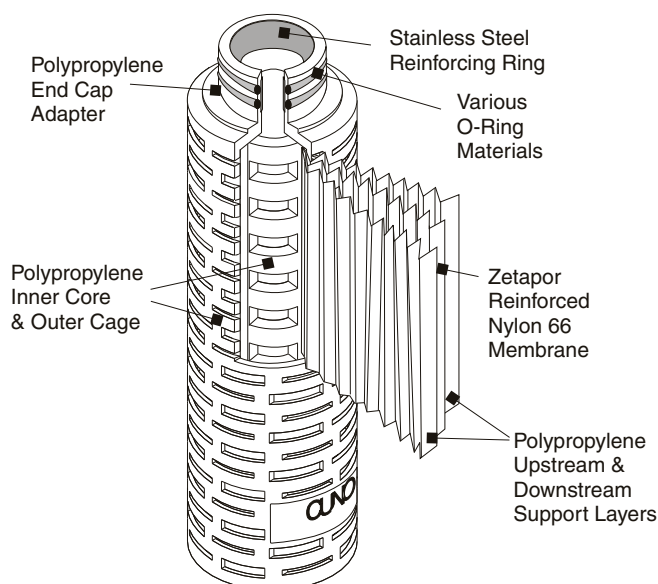
Chemical Compatibility

The Zetapor SP 0.45 µm cartridge exhibits a wide range of chemical compatibility. The compatibility data that follows (Table 1) are intended as a guide only. CUNO recommends that the compatibility of the chemical considered for use with the cartridge be established under actual process conditions because the operating parameters may affect the interaction between the cartridge and chemical. Consideration must also be given to the selection of suitable o-ring/gasket material to ensure complete compatibility.

TABLE 1 - CHEMICAL COMPATIBILITY		
Solution	Temperature (°C)	Compatibility
Acetic Acid 25%	22	G
Acetic Acid 70%	22	L
Acetic Acid Glacial	22	L
Acetone	22	G
Ammonia 10%	22	G
Acetonitrile	22	L
Acetonitrile	80	N
Ammonium Hydroxide 28%	22	G
Benzene	22	L
Benzyle Alcohol	22	G
n-Butanal	22	G
n-Butyl Acetate	22	G
Butyle Carbitol	22	G
Carbon Tetrachloride	22	L
Carbon Tetrachloride	77	N
Cellosolve Acetate	22	G
Cellosolve Solvent	22	G
Chloroform	22	N
Cotton Seed Oil	22	G
Cyclohexane	22	L
Cyclohexanone	22	L
Diethyl Acetamide	22	L
Diethyl Formamide	22	N
Dimethyl Formamide	22	N
Dimethyl Sulfoxide	22	L
Ethanol Absolute	22	G
Ethanol Absolute	28	L
Ethanol 50%	22	G
Ethyl Acetate	22	L
Ether, Diethyl	22	L
Ether, Diethyl	35	L
Ethylene Dichloride	22	G
Ethylene Glycol	22	G
Ethylene Oxide 12 - 88%	22	L
Formaldehyde 37%	22	G
Glycerol	22	G
n-Heptane	22	L
Hexane	22	L
Hydrochloric Acid 3.7%	22	N
Isobutyl Alcohol	22	G
Isopropyl Alcohol	22	G
Methanol	22	G
Methylene Chloride	22	N
Methyl Isobutyle Ketone	22	G
Monethanolamine	22	L
n-Propanol	22	G
Propylene Glycol	22	G
Pyridine	22	L
Sodium Hydroxide 10%	22	G
Sodium Hypochlorite	22	G
Toluene	22	L
Trichlorotrifluoroethane (Freon)	22	G
Water	22	G
Water	82	G
Xylene	22	L
Explanation of Ratings		
G = Good compatibility to the temperature indicated		
L = Limited compatibility - consult factory		
N = Not recommended		
Recommendations based on 4-hr. soak test		

CONSTRUCTION

The Zetapor SP 045 cartridge is produced from reinforced, pleated filter composite membrane containing two layers of charge-modified Nylon 66. The membrane is supported on both the up and downstream sides by polypropylene. Multiple lengths of various end cap styles are produced by thermoplastic bonding with no adhesives or surfactants used in the cartridge assembly. All materials used in the construction of Zetapor SP 045 cartridges are FDA (CFR 21) listed for food contact.



CARTRIDGE SPECIFICATIONS

When referring to Table 2, please note that all specifications are given **per 10" cartridge element**.

TABLE 2 - Zetapor SP 045 SPECIFICATIONS	
Rated Pore Size	0.45 micron
Filter Area	5.5 ft ²
Dimension (nominal)	2.8" outer diameter, lengths to 40" (see Ordering Guide)
Extractables	≤ 20 mg at 78°F (25°C)
Bacterial Removal Efficiency	10 ⁶ /cm ² <i>Serratia marcescens</i>
Diffusion Flow Rate	≤ 10 cc/min. at 25 psig
Pyrogenicity	≤ 25 pg/ml for first 250 ml
Oxidizable Substances	Negative after 1000 ml flush

OPERATING PARAMETERS

Maximum Operating Temperature	175°F (80°C)
Maximum Differential Pressure @ 78°F (25°C)	Forward: 65 psid (4.49 bar)
	Reverse: 65 psid (4.49 bar)
Sterilization	<i>In situ</i> steam or Autoclave to 293°F (145°C)
Recommended Rinse Volume	1000 ml (minimum) per 10" element

CUNO does not recommend reverse flow. Data indicates that cartridge integrity is maintained up to 65 psid maximum reverse pressure.

ZETAPOR SP 0.45 ORDERING GUIDE

Plant Code 08

Product Code 103

Type NMC

Basic Cartridge Design	Nominal Cartridge Length *	Gasket or O-Ring Material	Micron Rating	Formulation	Control Grade
70002 70003 70012 70025 70048	01 02 03 04	A - Silicone B - Fluorocarbon C - EPR D - Nitrile	045 (0.45 µm)	S	P - Pharmaceutical

*Specific lengths illustrated below

**SINGLE OPEN END
CODE 7 (226) O-RING
BAYONET LOCK PALL**

NOMINAL CARTRIDGE LENGTH	70002 L
01	10 3/16"
02	19 15/16"
03	29 11/16"
04	39 7/16"

**SINGLE OPEN END
CODE 8 (222) O-RING
CUNO & PALL**

NOMINAL CARTRIDGE LENGTH	70003 L
01	10 7/32"
02	19 31/32"
03	29 23/32"
04	39 15/32"

**SINGLE OPEN END
(222) O-RING
CUNO & MILLIPORE**

NOMINAL CARTRIDGE LENGTH	70012 L
01	10 1/4"
02	22"
03	31"

**SINGLE OPEN END
CODE 3 (222) O-RING
PALL**

NOMINAL CARTRIDGE. LENGTH	70025 L
01	10 7/32"
02	19 31/32"
03	29 23/32"
04	39 15/32"

**SINGLE OPEN END
(222) O-RING
CUNO**

NOMINAL CARTRIDGE LENGTH	70048 L
01	9 31/32"
02	19 23/32"

WARRANTY

Seller warrants its equipment against defects in workmanship and material for a period of 12 months from date of shipment from the factory under normal use and service and otherwise when such equipment is used in accordance with instructions furnished by Seller and for purposes disclosed in writing at the time of purchase, if any. Any unauthorized alteration or modification of the equipment by Buyer will void this warranty. Seller's liability under this warranty shall be limited to the replacement or repair, F.O.B. point of manufacture, of any defective equipment or part which, having been returned to the factory, transportation charges prepaid, has been inspected and determined by the Seller to be defective. THIS WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EITHER EXPRESSED OR IMPLIED, AS TO DESCRIPTION, QUALITY, MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE OR USE, OR ANY OTHER MATTER. Under no circumstances shall Seller be liable to Buyer or any third party for any loss of profits or other direct or indirect costs, expenses, losses or consequential damages arising out of or as a result of any defects in or failure of its products or any part or parts thereof or arising out of or as a result of parts or components incorporated in Seller's equipment but not supplied by the Seller.

Your local CUNO distributor is:

LENNTECH

info@lennotech.com Tel. +31-152-610-900

www.lennotech.com Fax. +31-152-616-289

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a 3M company

The below 3M Cuno -series cartridge filters are all the models that are potentially possible in all variations.
Please note that not all models are actually produced or on stock and some model numbers and names have become obsolete.
Nevertheless this should help as cross reference table chart for Cuno filters nomenclature.

Zetapor

7000201A45SP	7002501A45SP
7000201B45SP	7002501B45SP
7000201C45SP	7002501C45SP
7000201D45SP	7002501D45SP
7000202A45SP	7002502A45SP
7000202B45SP	7002502B45SP
7000202C45SP	7002502C45SP
7000202D45SP	7002502D45SP
7000203A45SP	7002503A45SP
7000203B45SP	7002503B45SP
7000203C45SP	7002503C45SP
7000203D45SP	7002503D45SP
7000204A45SP	7002504A45SP
7000204B45SP	7002504B45SP
7000204C45SP	7002504C45SP
7000204D45SP	7002504D45SP
7000301A45SP	7004801A45SP
7000301B45SP	7004801B45SP
7000301C45SP	7004801C45SP
7000301D45SP	7004801D45SP
7000302A45SP	7004802A45SP
7000302B45SP	7004802B45SP
7000302C45SP	7004802C45SP
7000302D45SP	7004802D45SP
7000303A45SP	7004803A45SP
7000303B45SP	7004803B45SP
7000303C45SP	7004803C45SP
7000303D45SP	7004803D45SP
7000304A45SP	7004804A45SP
7000304B45SP	7004804B45SP
7000304C45SP	7004804C45SP
7000304D45SP	7004804D45SP
7001201A45SP	
7001201B45SP	
7001201C45SP	
7001201D45SP	
7001202A45SP	
7001202B45SP	
7001202C45SP	
7001202D45SP	
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7001203B45SP	
7001203C45SP	
7001203D45SP	
7001204A45SP	
7001204B45SP	
7001204C45SP	
7001204D45SP	