

# 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

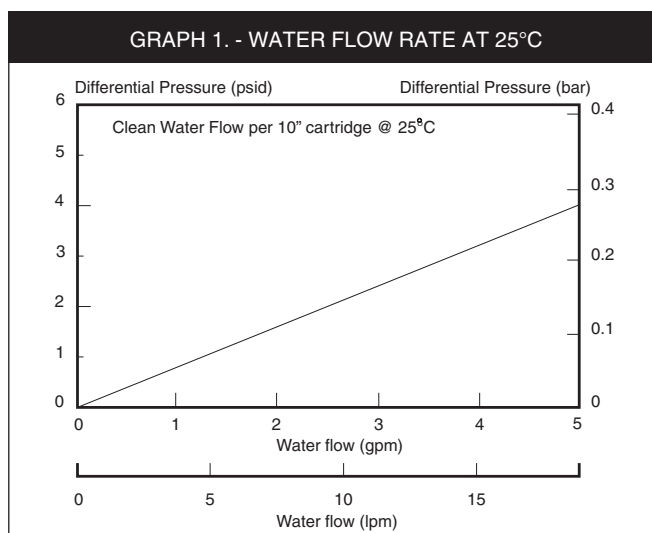
Bacterial removal to levels in excess of  $10^6$  cells/cm<sup>2</sup> was verified using ASTM challenge procedures with *Serratia marcescens* as the test organism.

### 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.



### 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	BENEFIT
■ Electropositive charge on Nylon 66 membrane	■ Enhanced particle removal & pyrogenic reduction
■ 100% Integrity tested before shipment	■ 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

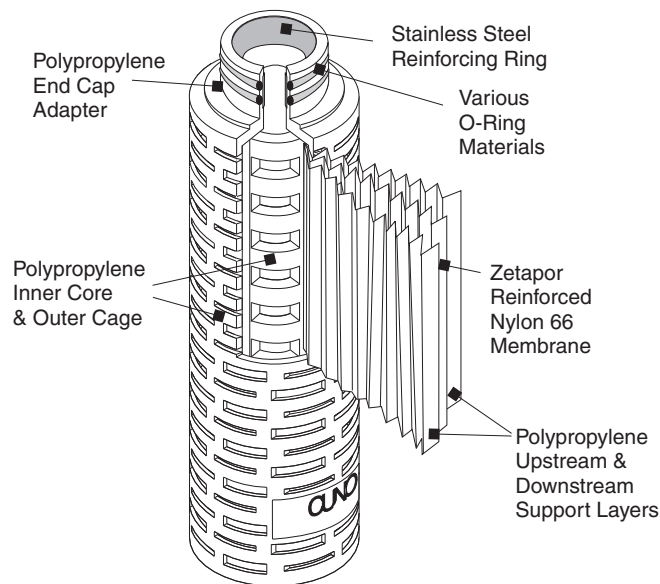
The Zetapor SP 0.45 µm cartridge exhibits a wide range of chemical compatibility. The compatibility data that follows (Table 1) are intended as a guide only. CUNO recommends that the compatibility of the chemical considered for use with the cartridge be established under actual process conditions because 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-Butonal	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 <sup>2</sup>
Dimension (nominal)	2.8" outer diameter, lengths to 40" (see Ordering Guide)
Extractables	≤ 20 mg at 78°F (25°C)
Bacterial Removal Efficiency	10 <sup>6</sup> /cm <sup>2</sup> <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

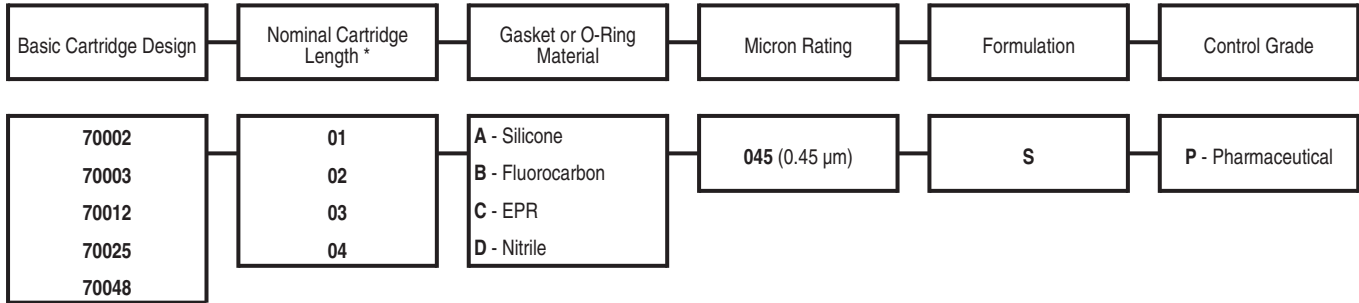
CUNO does not recommend reverse flow. Data indicates that cartridge integrity is maintained up to 65 psid maximum reverse pressure.

# ZETAPOR SP 0.45 ORDERING GUIDE

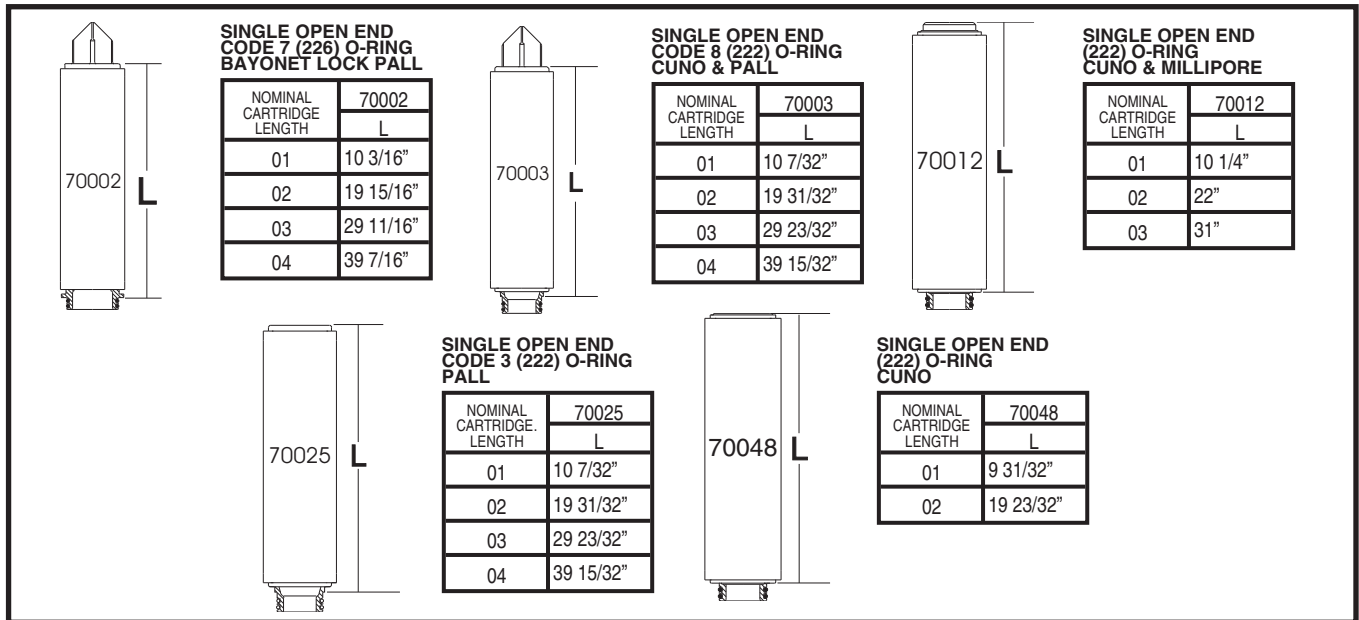
Plant Code 08

Product Code 103

Type NMC



\*Specific lengths illustrated below



## 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.

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