

## Posidyne® Positive Zeta Filter Cartridges



#### **Description**

Pall Posidyne® filter cartridges incorporate a patented covalent charge—modified Nylon 6,6 membrane which exhibits a net positively charged Zeta potential in aqueous solutions. This positive Zeta potential provides enhanced retention of fine particles smaller than the membrane's rating, such as endotoxins in water, in a direct flow mode without the higher pressure drop of finer filters. High area pleated into single open ended (SOE) AB sanitary style cartridges, N66 Posidyne filters are available in single layer particulate/bioreduction grades and in double layer sterilizing grades for added assurance of reliability in critical sterilizing applications.

- Inherently water wettable
- Resin and surfactant-free
- Positive Zeta potential
- Adsorption-enhanced retention of particles smaller than filter rating
- Removes endotoxins from water
- High protein recovery from sera and most protein solutions
- Low filter extractables
- 100% integrity tested
- Individually serialized
- Manufactured for use in conformance with cGMP
- ISO 9000 Certified Quality System
- Pharmaceutical "P" optimized grades with Certificate of Test provided
- Validation Guide available

#### **Specifications**

#### **Materials of Construction**

- FDA-listed materials per 21CFR
- Membrane: Nylon 6,6 covalently-modified positive Zeta, double layer
- Supports/Drainage/End Caps: Polyester
- Core/Cage: Polypropylene
- O-rings: Silicone

## Microbial Removal Ratings<sup>2</sup>

• NKKZ: 0.65 µm microbial rated

- NNXZ: 0.45 μm microbial rated (Typical Serratia marcescens T<sub>R</sub> >10<sup>9</sup>)
- NXZ, NLZ: 0.45 μm sterilizing grade
- NBAZ, NAZ: 0.2 μm microbial rated (Typical *Brevundimonas diminuta* T<sub>R</sub> >10<sup>4-6</sup>)
- NIZ: 0.1 μm microbial rated (Typical Brevundimonas diminuta T<sub>R</sub> >10<sup>9</sup>)
- NFZ: 0.2 μm sterilizing grade
- NTZ: 0.1 µm sterilizing grade
- NDZ: 0.04 μm rated, sterilizing grade (Typical MuLV, HIV (retrovirus) T<sub>R</sub> >10<sup>5</sup>)

### **Adsorptive Characteristics**

Endotoxin Removal Efficiency: 3

• >99.997% to ≥0.16 gm *E. coli* endotoxin

Polystyrene Bead Efficiency: 4

- NLZ, NAZ, NIZ to >1 gm loading: >99.99% for 0.04 µm beads
- NFZ, NTZ to >2-10 gm loading: >99.99% for 0.04 µm beads

## Configuration (AB Code 7)<sup>5</sup>

- Double 226 O-ring adapter
- Finned end, bayonet lock

#### **Dimensions (nominal)**

- Lengths: 10 in. (254 mm), 20 in. (508 mm), 30 in. (762 mm), 40 in. (1016 mm)
- Diameter: 2.75 in. (70 mm)

#### **Operating Conditions**

Max. Differential Pressure/Temp:<sup>6</sup>

- 80 psid (5.5 bard) to 122°F (50°C)
- 60 psid (4.1 bard) to 176°F (80°C)
- 30 psid (2.1 bard) to 257°F (125°C)

#### Autoclave/Steaming In Situ

• Cumulative Steam Exposure: 16 hrs (1 hr cycles) at 250°F (121°C), 4 hrs (1 hr cycles) at 284°F (140°C)

# Aqueous Extractables (NVR)<sup>8</sup>

• Per 10 in. (254 mm) element: Typically 15-25 mg

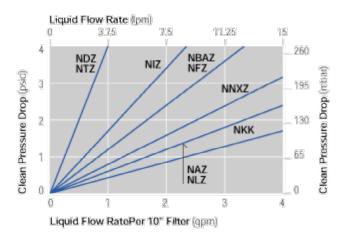
## Quality/Bio-Safety (P Grades)

- Integrity (100% Unit Release Test): Correlated to microbial retention.
- Biological Tests: Meets USP Biological Reactivity, In Vivo, for Class VI-121°C plastics.
- Effluent Quality Tests:<sup>9</sup>
  - ♦ Meets Cleanliness per USP Particulates in Injectables.
  - ♦ Non-Fiber-Releasing per 21CFR.

- ♦ Non-Pyrogenic per USP Bacterial Endotoxins (<0.25EU/ml).
- ♦ Meets Total Organic Carbon and Water Conductivity per USP Purified Water, pH per USP packaged waters.
- Steam Resistance: Lot samples multi-cycle autoclave challenged.

#### **Performance**

# Pressure Drop vs. Liquid Flow Rate<sup>10</sup>



## Filter Area / Integrity Test Volumes

Filter Area <sup>11</sup> ft <sup>2</sup> (cm <sup>2</sup> )	Forward Flow <sup>12</sup> cc/min at psi (mbar)		
8.5 (8000)	≤ 26	16 (1100)	
8.8 (8200)	≤ 22	18 (1240)	

<sup>&</sup>lt;sup>1</sup> Other polymers available.

<sup>&</sup>lt;sup>2</sup> Lot samples of sterilizing grades retain >10<sup>7</sup>cfu/cm<sup>2</sup> of an appropriate challenge organism per mod. ASTM F838–83 and FDA guidelines: NXZ, NLZ retains *Serratia marcescens*. NFZ, NTZ, NDZ retains *Brevundimonas diminuta*. NTZ also retains >10 <sup>7</sup>cm<sup>2</sup> *Acholeplasma laidlawii* mycoplasma.

<sup>&</sup>lt;sup>3</sup> Determined for 10 in (254 mm) elements challenged in deionized water. No endotoxin detectable in effluent using LAL reagent with sensitivity of <0.5EU/ml.

<sup>&</sup>lt;sup>4</sup> Determined for 10 in (254 mm) elements challenged in deionized water smaller than un-modified filter's microbial ratings. Capacity determined at breakthrough (effluent turbidity).

<sup>&</sup>lt;sup>5</sup> Alternate AB adapter codes available.

<sup>&</sup>lt;sup>6</sup> Using compatible fluids.

<sup>&</sup>lt;sup>7</sup> Lab tests to establish multi-cycle resistance. Filters should be qualified in actual use. Contact Pall for recommended procedures.

<sup>&</sup>lt;sup>8</sup> In water at 20-25°C after steaming.

<sup>&</sup>lt;sup>9</sup> Per lot sample soak or rinse-up flush aliquots.

8.8 (8200)	<u>≤</u> 15	25 (1725)
9.0 (8500)	≤ 85	30 (2060)
8.8 (8200)	≤ 20	30 (2060)
8.5 (7800)	≤ 12	40 (2760)
9.0 (8500)	≤ 50	50 (3440)
7.5 (7000)	≤ 14	75 (5175)
8.7 (8100)	<u>≤</u> 10	60 (4125)

 $<sup>^{10}</sup>$  Typical initial clean media  $^{\Delta}$ P per 10 in. (254 mm) element; water at 68°F (20°C); viscosity 1 centipoise. For assistance in filter assembly sizing and housing selection, contact your local Pall distributor.

### **Ordering Information**

Part Number* <sup>13</sup>	Length Code*	Removal Rating (No. Layers)	
AB* NKKZ7PH4	1, 2, 3 or 4	0.65 µm	(2L)
AB* NNXZ7PH4	1, 2, 3 or 4	1.2 μm/0.45 μm	(2L)
AB* NLZ7PH4	1, 2, 3 or 4	0.45 μm	(2L)
AB* NAZ7PH4	1, 2, 3 or 4	0.2 μm	(1L)
AB* NBAZ7PH4	1, 2, 3 or 4	0.45 μm/0.2 μm	(2L)
AB* NFZ7PH4	1, 2, 3 or 4	0.2 µm sterilizing	(2L)
AB* NIZ7EH4	1, 2, 3 or 4	0.1 μm	(1L)
AB* NTZ7PH4	1, 2, 3 or 4	0.1 µm sterilizing	(2L)
AB* NDZ7EH4	1, 2, 3 or 4	0.04 μm	(2L)

<sup>\*</sup> Select Length Code: 1=10in. (254 mm); 2=20 in. (508 mm); 3=30in. (762 mm); 4=40 in. (1016 mm). Dimensions are nominal.

<sup>&</sup>lt;sup>11</sup> Filter areas are per 10 in. (254mm) element. All dimensions are nominal.

<sup>&</sup>lt;sup>12</sup> Forward flow allowable limit per 10 in. (254mm) cartridge, water wet, air test gas. ND values confirm grade and installation. Sterilizing grade-correlated method and values available on request.

<sup>&</sup>lt;sup>13</sup> Z indicates positive Zeta potential for enhanced fine particle removal efficiency in aqueous service. Code 7 adapter is standard. See Appendix for alternate adapter descriptions and codes. P indicates optimized and qualified for pharmaceutical use including 100% Integrity Test and Certificate of Test provided. H4 suffix=Silicone O-rings (standard). See Appendix for available alternate

O-ring polymer codes.

Note: For other integrity test wetting fluids or methods, multi-element forward flow values, or for other information, contact your local Pall distributor.

**Specifications and Availability:** The information provided is a guide to the part number structure and possible options. Product availability may be subject to change without notice. All specifications are nominal. This literature was reviewed for accuracy at the time of publication. For current information on the products and test methodologies, consult your local Pall distributor.