Posidyne[®] Filter Cartridges

Positive Zeta Potential for Enhanced Retention of Fine Particles in Large-scale Processes





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 particulate and bioreduction grades and in sterilizing-grades.

Features and Benefits

- Inherently water wettable
- Resin and surfactant-free
- Positive Zeta potential
- 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

Note: These filters are also available in Kleenpak Nova capsule format.

Quality and Bio-Safety

Biological Tests

 Meets USP Biological Reactivity Test, in vivo, for Class VI-121 °C Plastics

Effluent Quality Tests*

- Meets Cleanliness per USP Particulates in Injectables
- Non-Fiber-Releasing
- Non-Pyrogenic per USP Bacterial Endotoxins (< 0.25 EU/mL)
- Meets Total Organic Carbon and Water Conductivity per USP Purified Water, pH per USP Sterile Purified Water

* Per lot sample soak or rinse-up flush aliquots.

Posidyne Filter Cartridges

Technical Specifications

Materials of Construction

| Membrane | Nylon 6,6, covalently-modified positive Zeta |
|--|--|
| Supports, Drainage and End Caps | Polyester |
| Core and Cage | Polypropylene |
| O-ring | Silicone ⁽¹⁾ |
| ⁽¹⁾ Other polymers available. | |

Microbial Removal Ratings⁽²⁾

| NNXZ | 0.45 μm microbial-rated (Typical Serratia marcesens T_{R} $>$ 10°) |
|-----------|--|
| NXZ, NLZ | 0.45 µm microbial-rated |
| NBAZ, NAZ | 0.2 μ m microbial-rated (Typical Brevundimonas diminuta T _B > 10 ⁴⁻⁶) |
| NIZ | 0.1 μm microbial-rated (Typical Brevundimonas diminuta T _B > 10 ⁹) |
| NFZ | 0.2 µm sterilizing-grade |
| NTZ | 0.1 µm sterilizing-grade |
| NDZ | 0.04 μm rated, sterilizing-grade (Typical MuLV, HIV (retrovirus) T _R 10 ^s) |

⁽²⁾ Lot samples retain > 10⁷ cfu/cm² of an appropriate challenge organism per mod. ASTM F838-83 and FDA guidelines; NXZ, NLZ: Serratia marcescens; NFZ, NTZ, NDZ: Brevundimonas diminuta; NTZ also retains > 10⁷ cfu/cm² Acholeplasma laidlawii mycoplasma.

Nominal Dimensions

| 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⁽³⁾

| Maximum Differential | 5.5 bard (80 psid) to 50 °C (122 °F) |
|--------------------------|---------------------------------------|
| Pressure and Temperature | 4.1 bard (60 psid) to 80 °C (176 °F) |
| | 2.1 bard (30 psid) to 125 °C (257 °F) |

⁽³⁾ Using compatible fluids.

Configuration (AB Code 7)⁽⁴⁾

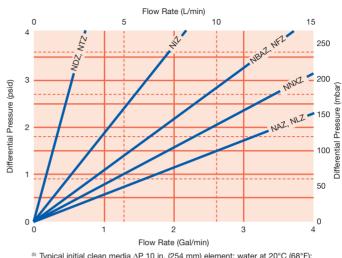
| D | ~~~ | <u> </u> | | |
|----------|-----|----------|---------|--|
| Double | 226 | O-ring | adapter | |

Fin end with bayonet lock

⁽⁴⁾ Alternate adapter codes available.

Ordering Information

Typical Liquid Flow Rate⁽⁵⁾



⁽⁶⁾ Typical initial clean media ΔP 10 in. (254 mm) element; water at 20°C (68°F); viscosity 1 cP. For assistance in filter assembly sizing and housing selection, contact your local Pall representative.

Autoclavable or steamable in situ⁽⁶⁾

| Cumulative Steam Exposure | 16 hours (1-hour cycles) at 121 °C (250 °F) |
|---------------------------|--|
| | 4 hours (1-hour cycles) at 140 °C (284 °F) |
| | |

Laboratory tests to establish multi-cycle resistance. Filters should be qualified in actual use. Contact Pall for recommended procedures.

Aqueous Extractables (NVR) per 10 in. (254 mm) Element

Typically 15 - 25 mg

Particle Removal Efficiencies

traceability.

| Endotoxin Removal Efficiency ⁽⁷⁾ | > 99.997% to 0.16 gm <i>E.</i> coli endotoxin | | | | |
|--|--|--|--|--|--|
| Polystyrene Bead Efficiency® | 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 | | | | |

 $^{\prime\prime}$ Determined for 10 in. (254 mm) elements challenged in deionized water. No endotoxin detectable in effluent using LAL reagent with sensitivity of < 0.5 EU/mL.

Determined for 10 in. (254 mm) elements challenged in deionized water. Capacity determined at breakthrough (effluent turbidity).

| Orach | | | | | | | | | | | |
|-------|----------------------|------|-------------------|--|--|--|--------------------------|-------------|------------------|--|--|
| АВ | | | | | | 7 | | | | | |
| Code | Nominal Length | Code | Removal Rating | Filter Area ⁷⁷ | Forward Flow mL/min at mbar (psi) [®] | Code | Filter Grade | Code | Gasket Option | | |
| 1 | 10 in. | NNXZ | 1.2/0.45 µm | 0.82 m² (8.8 ft²) | 22 at 1240 (18) | Р | Pharmaceutical* | H4 | Silicone | | |
| | (254 mm) | NLZ | 0.45 µm | 0.82 m ² (8.8 ft ²) | 15 at 1725 (25) | Omit | General Use | | rials available | | |
| 2 | 20 in. | NAZ | 0.2 µm | 0.85 m ² (9.0 ft ²) | 85 at 2060 (30) | * Pall pharr | naceutical-grade filters | on request. | | | |
| | (508 mm) | NBAZ | 0.45/0.2 µm | 0.82 m ² (8.8 ft ²) | 20 at 2060 (30) | | are designed for use in | | | | |
| 3 | 3 30 in. (762 mm) | NFZ | 0.2 µm | 0.78 m ² (8.5 ft ²) | 12 at 2760 (40) | conformance with CGMP in Manufacturing, Processing, | | | | | |
| 4 | 40 in. | NIZ | 0.1 µm | 0.85 m ² (9.0 ft ²) | 50 at 3440 (50) | | or Holding of Drugs | | | | |
| | (1016 mm) | NTZ | 0.1 µm | 0.70 m ² (7.5 ft ²) | 14 at 5175 (75) | (21CFR210) and CGMP for finished Pharmaceuticals (21CFR211.72) including batch release certificate and full | | | | | |
| | | NDZ | 0.04 µm | 0.81 m ² (8.7 ft ²) | 25 at 3440 (50) | | | | | | |
| | | | | | | | | | | | |

77 Filter areas are per 10 in. (254 mm) element. All dimensions are nominal.

Forward Flow allowable limit for one 10 in. (254 mm) cartridges at given test pressure, water wet, air test gas. Please contact Pall for method details and test parameters