



Kleenpak™ Capsules with Posidyne® Membrane

Description

Pall Kleenpak capsule filters with intrinsically hydrophilic positive zeta potential **Posidyne** membrane are rugged, self-contained sanitary filters designed for small-batch sterile filtration of aqueous <u>pharmaceutical</u> solutions. With a net positive charge in most aqueous solutions from pH 3 to 10, Kleenpak Capsules with Posidyne Membrane Assemblies can be effective in removing contaminants such as cell debris and endotoxin smaller than the filter rating.

Features and Benefits

- Positive Zeta potential for enhanced efficiency in aqueous solutions
- Double-layer sterilizing membranes for high reliability
- 100% integrity and pressure-tested
- · High protein recovery from serum and most protein solutions
- 0.2 μm NF grade for sterilization
- 0.1 µm NT grade for diminutive bacteria and mycoplasma removal
- Low filter extractables
- · Sanitary vent and drain valves with non-twist hose barbs
- Upstream hold-up volumes (< 1 mL)
- Repeatedly autoclavable
- · Manufactured for use in conformance with cGMP
- ISO 9000 Certified Quality System
- Pharmaceutical P optimized
- Certificate of Test provided

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 Sterile Purified Water

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

Autoclave Resistance

• Lot samples multi-cycle autoclave challenged

Specifications

Materials of Construction

Membrane Nylon 6,6, positively-charged

Support and Drainage Polyester

Core and Cage Autoclavable Version: Polypropylene

G and S Grades: Polyester

End Caps and Shell Polyester

Vent and Drain Valve O-ring Ethylene Propylene (EPDM)

Microbial Removal Ratings

NFZ 0.2 μm , sterilizing-grade¹ NTZ 0.1 μm , sterilizing-grade²

Nominal Filter Areas

| Size Code | KA1 | KA2 | KA3 | KA4 |
|-----------------------|-------------------------|----------------------|------------------------|------------------------|
| Effective Filter Area | 0.05 m^2 | 0.1 m ² | 0.2 m ² | 0.5 m^2 |
| | (0.53 ft ²) | (1 ft ²) | (2.1 ft ²) | (5.3 ft ²) |

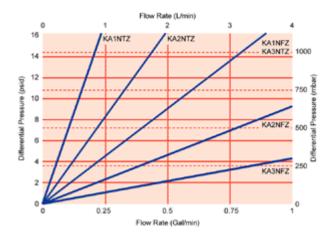
Nominal Dimensions

| Size Code | KA1 | KA2 | KA3 | KA4 |
|--|---------------------|---------------------|---------------------|----------------------|
| Maximum Diameter of Bowl (including Valves) | 94 mm (3.7 in.) | 94 mm (3.7 in.) | 109 mm (4.2 in.) | 109 mm (4.2 in.) |
| Length (including Sanitary Connection [Code 1]) | 117 mm (4.6 in.) | 158 mm (6.2 in.) | 174 mm (6.8 in.) | 286 mm (11.2 in.) |
| Length (including Stepped Hose Barb Connection [Code 2]) | 158 mm (6.2 in.) | 199 mm (7.8 in.) | - | - |
| Length (including Hose Barb Connection [Code 6]) | - | - | 210 mm (8.2 in.) | 325 mm (12.7 in.) |

¹ Assembly lot samples retain > 10⁷ cfu/cm² of *Brevundimonas diminuta* per mod. ASTM F838-83 and FDA guidelines.

² Also retains > 10⁷ cfu/cm² *Acholeplasma laidlawii* mycoplasma.

Typical Liquid Flow Rates⁴



⁴ Typical initial clean Δ P, water at 20 °C, 1 cP. KA4NFZP Δ P flow is 37 mbard/L per min (2.1 psid/gpm). Pressure drops at other flows are directly proportional to flow. Values shown for 38 mm (1½ in.) sanitary flange connections. Values with other connections are available on request. For assistance, contact your local Pall representative.

Aqueous Extractables (NVR)⁵ (Non G and S Grades)

| KA1 | KA2 | KA3 | KA4 |
|------|-------|-------|-------|
| 6 mg | 12 mg | 20 mg | 40 mg |

⁵ Water at 20 – 25 °C after autoclaving.

Steam Autoclaving⁶ (Non G and S Grades)

Cumulative Autoclave Time

16 hours at 125 ℃ 4 hours at 140 ℃

Warning: Kleenpak filters must not be steam-sterilized in situ by passing steam through under pressure.

Sterilization

Gamma-irradiation Maximum Dosage (G Grade)

35 kGy

³ Using compatible liquids. Maximum 3.5 barg (50 psig) in air/gas service.

⁶ Laboratory tests (1-hour cycles) establish multi-cycle.

| Orderin | ng Information | | | | | | |
|---------|-------------------------|------|--------------------------|------|---------------------------------|--------|--------------------|
| KA _ | | P | | P | | \Box | |
| Code | Size and Area | Code | Removal Ratings | Code | Inlet and Outlet Connections | Code | Options |
| 1 | | NFZ | 0.2 µm sterilizing-grade | 1 | 38 mm (1% in.) sanitary flange | Blank | Autoclave service |
| 2 | See above dimensions | NTZ | 0.1 µm sterilizing-grade | 2 | 6 - 13 mm (¼ - ½ in.) hose barb | G | Unsterilized, |
| 3 | table | | | 6 | 14 mm (% in.) hose barb | | Gamma-irradiatable |
| 4 | | | | | | s | Pre-sterilized |

Note: Contact Pall for specific part number availability.
S and G grades are available in KA2 with inlet and outlet option 1; KA3 with with inlet and outlet option 6.
Autoclassible grades available in KA1 and KA2 with inlet and outlet options 1 and 2; KA3 and KA4 with with inlet and outlet options 1 and 6.

Contact Information

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