



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 [pharmaceutical](#) 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-grade ¹
NTZ	0.1 µm, sterilizing-grade ²

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.

Nominal Filter Areas

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

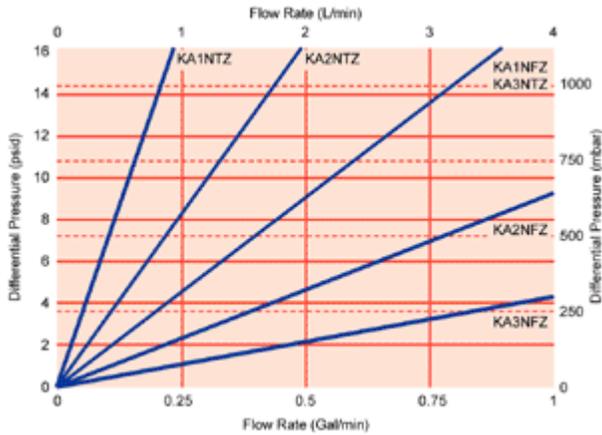
Operating Conditions³

Maximum Pressure and Temperature
Maximum Differential Pressure

5.2 barg (75 psig) to 40 °C
4.1 barg (60 psid) at 40 °C

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

Typical Liquid Flow Rates⁴



⁴ Typical initial clean ΔP , water at 20 °C, 1 cP. KA4NFZP ΔP flow is 37 mbar/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 °C
4 hours at 140 °C

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

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

Ordering Information

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KA 				P 			
Code	Size and Area	Code	Removal Ratings	Code	Inlet and Outlet Connections	Code	Options
1	See above dimensions table	NFZ	0.2 µm sterilizing-grade	1	38 mm (1½ in.) sanitary flange	Blank	Autoclave service
2		NTZ	0.1 µm sterilizing-grade	2	6 – 13 mm (¼ – ½ in.) hose barb	G	Unsterilized, Gamma-irradiatable
3				6	14 mm (½ in.) hose barb	S	Pre-sterilized
4							

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.
 Autoclavable 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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This information is accurate as of the revision date indicated.