

Kleenpak™ Capsules with Ultipor® N66 Membrane Assemblies

0.1 µm and 0.2 µm Capsules with Excellent Wettability



Pall **Kleenpak** sterilizing-grade capsule filters with intrinsically hydrophilic **Ultipor** N66 membrane are self-contained sanitary filters designed for convenient small-batch sterile filtration of most pharmaceutical solutions. Rugged, compact design ensures reliability.

Features and Benefits

- 100% integrity and pressure tested
- 0.2 micron NFP sterilizing-grade
- 0.1 micron NTP sterilizing-grade for bacteria and mycoplasma removal
- Low filter extractables
- Excellent solvent compatibility
- Sanitary vent and drain valves with non-twist hose bars
- Low hold-up volumes (< 1 mL)
- Gamma-irradiatable, autoclavable, and pre-sterilized versions available for maximum flexibility
- Autoclavable versions can be repeatedly autoclaved
- 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

Integrity

- Every filter tested during manufacture. Test correlated to microbial retention

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

Autoclave Resistance

- Lot samples multi-cycle autoclave challenged

* Per lot sample or rinse-flush aliquots.

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Technical Specifications

Materials of Construction

Membrane	Nylon 6,6
Support and Drainage	Polyester
Core and Cage	Autoclavable Version: Polypropylene
	G and S Grades: Polyester
End Caps and Shell	Polyester
Valve O-rings	Ethylene Propylene (EPDM)

Microbial Removal Ratings⁽¹⁾

NF	0.2 µm, sterilizing-grade, <i>Brevundimonas diminuta</i> .
NT	0.1 µm, sterilizing-grade, ⁽²⁾ <i>Brevundimonas diminuta</i> .

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

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

Nominal Filter Areas

Size Code	KA1	KA2	KA3	KA4
Effective Filter Area				
NF:	0.05 m ² (0.5 ft ²)	0.1 m ² (1 ft ²)	0.2 m ² (2 ft ²)	0.5 m ² (5 ft ²)
NT:	0.045 m ² (0.4 ft ²)	0.08 m ² (0.8 ft ²)	0.2 m ² (2 ft ²)	0.4 m ² (4 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* [Codes 1 and 8])	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])	158 mm (6.2 in.)	199 mm (7.8 in.)	210 mm (8.2 in.)	325 mm (12.7 in.)

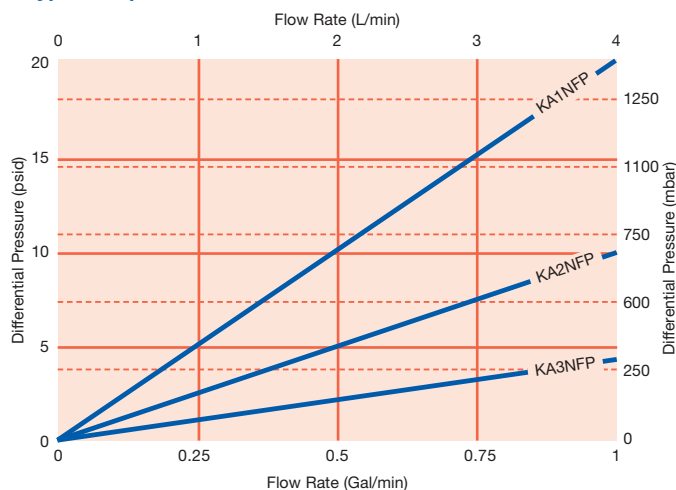
* Sanitary connection is Tri-Clamp compatible. Tri-Clamp is a trademark of Alfa Laval, Inc.

Operating Conditions⁽³⁾

Maximum Pressure and Temperature	5.2 barg (75 psig) to 40 °C (104 °F)
Maximum Operating Differential Pressure	4.1 barg (60 psid) at 40 °C (104 °F)

⁽³⁾ Using compatible liquids. Recommended maximum 3.5 barg (50 psig) in continuous air and gas service. KA*NT filters may be forward flow tested at 5171 mbar (75 psig) at ambient temperature.

Typical Liquid Flow Rates⁽⁴⁾



⁽⁴⁾ Typical initial clean ΔP; water at 20 °C (68 °F), 1 cP. Values shown are 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⁾

Size Code	KA1	KA2	KA3	KA4
Non-irradiated	7 mg	10 mg	12 mg	20 mg
Pre-sterilized	6 mg	12 mg	22 mg	N/A

⁽⁵⁾ In water at 20 – 25 °C (68 – 77 °F) after autoclaving. N/A = Filter not available.

Steam Autoclaving⁽⁶⁾

Cumulative Autoclave Time	16 hours at 125 °C (257 °F) 4 hours at 140 °C (284 °F)
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⁽⁶⁾ Laboratory tests (1-hour cycles) establish multi-cycle resistance. Filters should be qualified in actual use. Contact Pall for recommended procedures.

Warning: Kleenpak filters must be steamed in situ by passing steam through under pressure.

Sterilization

Gamma-irradiation	Maximum Dosage (G grade): 50 kGy
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Note: Contact Pall for specific part number availability.

S and G grades available in KA1 and KA2 with inlet and outlet options 1 and 2; KA3 with inlet and outlet options 1 and 6.

Autoclavable grades available in KA1 and KA2 with inlet and outlet options 1 and 2; KA3 and KA4 with inlet and outlet options 1 and 6.

Ordering Information

Code	Size and Area	Code	Removal Ratings	Code	Inlet and Outlet Connections	Code	Options
1	See above dimensions table	NF	0.2 µm sterilizing-grade	1	1 – 1½ in. sanitary flange	Blank	Autoclave service
2		NT	0.1 µm sterilizing-grade	2	6 – 13 mm (¼ – ½ in.) stepped hose barb	G	Unsterilized, Gamma-irradiatable
3				6	14 mm (⅝ in.) hose barb	S	Pre-sterilized
4				8	½ – ¾ in. fractional sanitary flange		

Option P8 available in KA2, autoclave service.