

# Kleenpak™ Capsules with Fluorodyne® II Membrane Assemblies

## Ideal for Sterile Filtration of Biopharmaceutical Fluids



Pall **Kleenpak** capsule filters with hydrophilic PVDF **Fluorodyne** II membrane are rugged, self-contained sanitary filters designed for small-batch sterile filtration of most pharmaceutical solutions. They are especially suitable for recovery of dilute preservatives, proteins, or other critical components, or may be used where higher throughput/higher flow rate PVDF membranes are preferred. A wide range of sizes is available.

### Features and Benefits

- Higher flow rates and throughputs
- Lowest binding membrane
- 100% integrity and pressure tested
- Lowest filter extractables
- Compatible with caustic solutions
- Sanitary vent and drain valves with non-twist hose barbs
- Low 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

#### 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 soak or rinse-up flush aliquots.

# Kleenpak Capsules with Fluorodyne II Membrane Assemblies

## Technical Specifications

### Materials of Construction

<b>Membrane</b>	Polyvinylidenedifluoride (PVDF), Double-layer
<b>Support, Drainage, Core, Cage, End Caps and Shell</b>	Polypropylene
<b>Vent and Drain Valve O-ring</b>	Ethylene Propylene (EPDM)

### Microbial Removal Ratings

DBL <sup>(1)</sup>	0.45 µm, microbial-rated
DFL <sup>(2)</sup>	0.2 µm, sterilizing-grade
DJL <sup>(3)</sup>	0.1 µm, mycoplasma-rated sterilizing-grade

<sup>(1)</sup> Typical *Lactobacillus brevis* titer reduction is > 10<sup>6</sup>.

<sup>(2)</sup> Assembly lot samples retain > 10<sup>7</sup> CFU/cm<sup>2</sup> of *Brevundimonas diminuta* per mod. ASTM F838-83 and FDA guidelines.

<sup>(3)</sup> DJL grade filters have high removal efficiency for diminutive organisms (e.g., typical titer reductions for *Acholeplasma laidlawii* is > 10<sup>8</sup>).

### Nominal Filter Areas

Size Code	KA1	KA2	KA3	KA4
<b>Effective Filter Area</b>	0.04 m <sup>2</sup> (0.4 ft <sup>2</sup> )	0.08 m <sup>2</sup> (0.8 ft <sup>2</sup> )	0.15 m <sup>2</sup> (1.5 ft <sup>2</sup> )	0.34 m <sup>2</sup> (3.4 ft <sup>2</sup> )

### Operating Conditions<sup>(4)</sup>

<b>Maximum Pressure and Temperature</b>	5.2 barg (75 psig) to 40 °C (104 °F)
<b>Maximum Differential Pressure</b>	4.1 bard (60 psid) at 40 °C (104 °F)

<sup>(4)</sup> Using compatible liquids. Maximum 3.5 barg (50 psig) in air/gas service.

### Sterilization

<b>Gamma-irradiation</b>	Maximum Dosage (G grade): 50 kGy
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### Nominal Dimensions

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

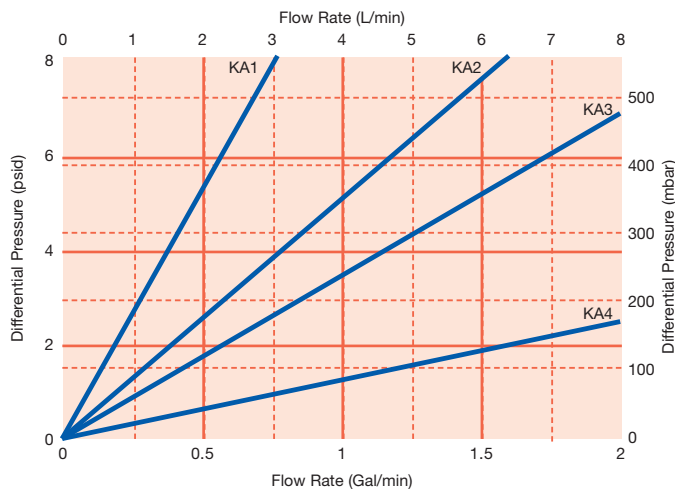
### Ordering Information

Code	Size and Area	Code	Removal Ratings	Code	Inlet and Outlet Connections	Code	Options
1	See above dimensions table	DBL	0.45 µm	1	38 mm (1½ in.) sanitary flange	Blank	Autoclave service
2		DFL	0.2 µm sterilizing-grade	6	14 mm (½ in.) hose barb	G	Unsterilized, Gamma-irradiatable
3		DJL	0.1 µm sterilizing-grade			S	Pre-sterilized
4							

**Notes:** Contact Pall for specific part number availability.

DBL available in sizes KA1, KA2, KA3, and KA4 with Inlet and outlet 1 and 6 in autoclavable version. DBL is also available in KA2 size, G and S grade with 1 and 6 in inlet and outlet options. DFL available in sizes KA1 and KA2 with inlet and outlet options 1 and 2 for G, S and autoclavable versions. DFL available in sizes KA3 and KA4 with inlet and outlet options 1 and 6 for G, S and autoclavable versions. DJL available in sizes KA1, KA2, KA3, and KA4 with Inlet and outlet 1 and 6 in G and S versions.

### Typical Liquid Flow Rates for DFL Media<sup>(6)</sup>



<sup>(6)</sup> Typical initial clean media ΔP per 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.

### Aqueous Extractables (NVR)<sup>(6)</sup>

<b>KA1 and KA2</b>	1 mg
<b>KA3</b>	2 mg
<b>KA4</b>	4 mg

<sup>(6)</sup> Water at 20 – 25 °C (68 °F – 77 °F) after autoclaving.

### Steam Autoclaving (Non-G and Non-S Grades)<sup>(7)</sup>

<b>Cumulative Autoclave Time</b>	30 hours at 125 °C (257 °F) 10 hours at 140 °C (284 °F)
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<sup>(7)</sup> Laboratory tests (1-hour cycles) establish multi-cycle.

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