Pall Corporation

Kleenpak™ Capsules with Fluorodyne® II DJL Membrane

Description

This 0.1 µm rated filter with serial layer (0.2/ 0.1 µm) membrane construction assures high flow rates compared to other 0.1 µm filters, and even some 0.2 µm filters. The grade DJL filter is validated for retention of *Acholeplasma laidlawii* ATCC 28206 at typically 10^8 TR (9 LRV) and retention of *Brevundimonas diminuta* ATCC 19146 at 10^7 cfu/cm^2 EFA, LRV > 11. This allows for enhanced sterilization assurance as well as efficient mycoplasma control at high flow rates, comparable to 0.2 µm PVDF membrane.

Pall Kleenpak™ capsules are rugged and compact filter capsules available with a broad range of filter media and in 4 different sized formats designed for a variety of small to large scale pharmaceutical manufacturing applications with volumes of 30 L to 1000 L.

Key Features and Benefits

- Highest flow compared to other 0.1 µm filters
- Built in prefiltration layer
- High safety for *A. laidlawii* (8 log)
- Sterilizing grade claim
- Low extractables
- High protein transmission
- Rapid preservative recoveries
- Easy integrity testing
- Compatible with organic solvents, acids and chemicals[1]
- Resin and surfactant-free
- Melt-sealed, non shedding

[1] Except ketones and amides

Quality Standards

- Manufactured for use in conformance with cGMP
- 100% integrity tested
- ISO 9000 Certified Quality System
- Meets USP Biological Reactivity Test, in vivo, for Class VI-121 ℃ Plastics
- Every filter tested during manufacture. Test correlated to microbial retention
- Certificate of Test provided includes:
  - Fabrication Integrity
  - Bacterial Retention
  - Materials of constructions
  - Effluent quality for cleanliness, TOC and Water Conductivity, pH and Pyrogens

Specifications

Materials of Construction

Filter Membrane	Hydrophilic modified PVDF
Support/Drainage	Polypropylene
End Cap, Core and Cage	Polypropylene
Capsule Shell	Polypropylene
Sealing Technology	Thermal bonding without adhesives

Extractables[1]

Typical Extractables in Water at 20 °C	All Styles < 5 mg per capsule

[1]Tested on capsules without pre-flushing

Nominal Effective Filter Area (EFA)

KA1	400 cm^2 (0.4 ft^2)
KA2	800 cm^2 (0.9 ft^2)
KA3	1500 cm^2 (1.6 ft^2)
KA4	3300 cm^2 (3.6 ft^2)

Operating Parameters[2]

Maximum Temperature	40 °C
Maximum Operating Pressure	5.2 bar (75 psi) at 20 °C 4.0 bar (58 psi) at 40 °C
Maximum Differential Pressure (forward direction)	4.0 bar (58 psi) at 40 °C

[2] In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction

Sterilization[3]

Autoclavable “G” Version	5 x 60 minutes at 140 °C
Autoclavable “S” Version	1 x 30 minutes at 125 °C
Gamma Irradiation	Maximum of 50 kGy

[3] Kleenpak capsules must not be sterilized in-situ by passing steam under pressure

Nominal Dimensions

	KA1	KA2	KA3	KA4
Diameter incl. Valves	94 mm (3.7 in.)	94 mm (3.7 in.)	105 mm (4.1 in.)	105 mm (4.1 in.)
Length - Code 1	117 mm (4.6 in.)	157 mm (6.2 in.)	174 mm (6.8 in.)	287 mm (11.3 in.)
Length - Code 2	158 mm (6.2 in.)	198 mm (7.8 in.)	-	-
Length - Code 6	157 mm (6.2 in.)	157 mm (6.2 in.)	210 mm (8.3 in.)	327 mm (12.8 in.)
Length - Code 12	137 mm (5.4 in.)	177 mm (7.0 in.)	-	-
Length - Code 16	137 mm (5.4 in.)	177 mm (7.0 in.)	192 mm (7.6 in.)	305 mm (12.0 in.)

Typical Flow Rates

This data will be added shortly.

If you requrie flow rate information urgently, please contact Pall.

Contact Information

Visit us on the Web at www.pall.com