Pall Corporation

Mini 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.

The Mini Kleenpak™ KA02 capsules are compact filters used in the laboratory for volumes of 2 L to 50 L in process development, and in pilot and manufacturing scale operations if processing requirements do not demand a large filter. These filters are the smallest capsule filters in the Upscale^{SM} Program range to utilize a pleated membrane, and are excellent for modelling filter performance at large production scale.

Key Features and Benefits

- Encapsulated format for higher flexibility, minimized cleaning and low installation costs
- Minimal hold up volume
- Ideal for upscale trials
- 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
Capsule Shell	Polypropylene
Filling Bell	Polycarbonate
Sealing Technology	Thermal bonding without adhesives

Operating Parameters[1]

Maximum Temperature	40 °C
Maximum Operating Pressure	4.1 bar (60 psi) at 40 °C
Maximum Differential Pressure (forward direction)	4.1 bar (60 psi) at 40 °C

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

Sterilization[2]

Autoclave	3 x 60 minutes at 140 °C
Gamma Irradiation	Maximum of 50 kGy

[2] • Pre-sterilized Mini Kleenpak capsules must not be re-sterilized.
• Mini Kleenpak capsules must not be sterilized in-situ by passing steam under pressure

Typical Extractables in Water at 20 °C [3]

“G” version	< 1 mg
“S” version	< 5 mg

[3] Tested on capsules without pre-flushing

Nominal Effective Filter Area (EFA)

200 cm^2 (0.22 ft^2)

Nominal Dimensions

Maximum Diameter Including Valves	41 mm (1.6 in.)
Length - Code 2	105 mm (4.1 in.)
Length - Code 8	73 mm (2.9 in.)

Typical Liquid Flow

Flow data will be added shortly.

If you require flow data urgently, please contact Pall.

Contact Information

Visit us on the Web at www.pall.com