



**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<sup>8</sup> TR (9 LRV) and retention of *Brevundimonas diminuta* ATCC 19146 at 10<sup>7</sup> cfu/cm<sup>2</sup> 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<sup>SM</sup> 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<sup>1</sup>
  - Resin and surfactant-free
  - Melt-sealed, non shedding
- <sup>1</sup> 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 °C 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<sup>1</sup>

|   |                           |
|---|---------------------------|
| 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 |

<sup>1</sup> In compatible fluids which do not soften, swell or adversely affect the filter or its materials of construction

### Sterilization<sup>2</sup>

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

- <sup>2</sup> • 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<sup>3</sup>

|             |        |
|-------------|--------|
| “G” version | < 1 mg |
| “S” version | < 5 mg |

<sup>3</sup> Tested on capsules without pre-flushing

### Nominal Effective Filter Area (EFA)

200 cm<sup>2</sup> (0.22 ft<sup>2</sup>)

### 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.

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### Contact Information

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