



Pall Corporation

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## Mini Kleenpak™ 20 Capsules with Fluorodyne® II DFL Membrane

### Description

These validated 0.2 micron-rated sterilizing grade filters retain *Brevundimonas diminuta* (ATCC 19146) at  $10^7$  CFU/cm<sup>2</sup> effective filter area (EFA) and ensure very low extractables and adsorption. They are recommended for sterilizing filtration of pharmaceutical fluids including solutions with active ingredients, biologicals, biotech proteins, ophthalmics and other dilute preservative solutions.

Mini Kleenpak 20 capsules are suited to both the filtration of low volumes of fluids (50 mL to 2 L) in the laboratory for filterability purposes, or in a GMP production environment where a certified filter product is essential and a single-use alternative to the cleaning of 47 mm disc holders is desired.



### Key Features and Benefits

- ▶ Ideal for screening trials
- ▶ Highest flow of PVDF of comparable PVDF filters
- ▶ 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
  - Material of Construction
  - Effluent quality for cleanliness, TOC and water conductivity, pH and pyrogens

### Specifications

#### Materials Of Construction

|                                         |                                               |
|-----------------------------------------|-----------------------------------------------|
| Filter Membrane                         | Hydrophilic modified PVDF                     |
| Housing, Vent Plug and Support Material | Polypropylene (Filling Bell is polycarbonate) |
| Sealing Technology                      | Thermal bonding without adhesives             |

#### Operating Parameters<sup>1</sup>

|                                            |                           |
|--------------------------------------------|---------------------------|
| Maximum Operating Temperature and Pressure | 1.4 bar (20 psi) at 20 °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>

Pre-sterilized, subject to a minimum of 25 kGy of gamma irradiation

<sup>2</sup> Pre-sterilized Mini Kleenpak 20 capsules must not be re-sterilized. Mini Kleenpak 20 capsules must not be sterilized *in-situ*

by passing steam under pressure

### Typical Hold up Volume

< 2.5 mL

### Nominal Dimensions

|                  |                 |
|------------------|-----------------|
| Capsule Length   | 83 mm (3.3 in.) |
| Capsule Diameter | 67 mm (2.7 in.) |

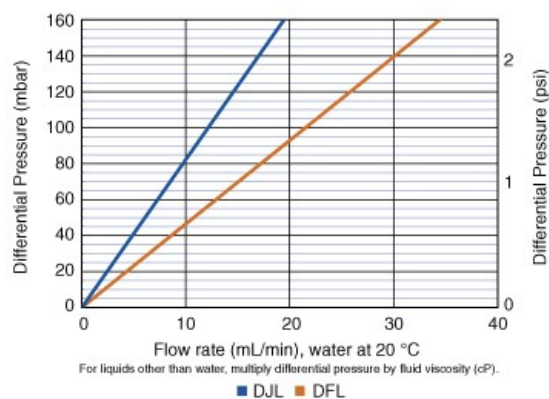
### Nominal Effective Filter Area (EFA)

20 cm<sup>2</sup> (3.1 in.<sup>2</sup>)

### Connection

¼ – ½ in. (6 – 13 mm) stepped hose barb. Inner bore to accept female slip luer interior and outer diameter to accept filling bell outlet

### Typical Liquid Flow vs. Differential Pressure



### Ordering Information

| Item                                                        | Part Number |
|-------------------------------------------------------------|-------------|
| Mini Kleenpak™ 20 Capsules with Fluorodyne® II DFL Membrane | KM5DFLP2S*  |

\* supplied as 1 box of 3 filters

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