



Data Sheet

# Fortis™ SL

## Solvent Filtration Cartridge Filters

### RELIABLE API FILTRATION DESIGNED TO FIT YOUR NEEDS



For the aseptic processing of solvent-based active pharmaceutical ingredients, Millipore's Fortis SL cartridge filters offer superior bacterial retention, efficient particle removal and consistent performance across the life of the filter. With the quality you expect from a Millipore filter and broad chemical and caustic compatibility of polytetrafluoroethylene (PTFE), these filters are ideal for use in the manufacture of active pharmaceutical ingredients containing methylene chloride, acetone, isopropyl alcohol, ethyl acetate and other organic solvents. Fortis SL cartridge filters are available in 10-, 20-, and 30-inch sizes.

#### Benefits

- Ideal for sterile manufacture of active pharmaceutical ingredients (API)
- Suitable for filtration of a wide variety of organic solvents
- Easy scale-up to meet changing process needs

## RELIABILITY

Fortis SL cartridge filters promote a consistent, repeatable manufacturing process characterized by high-capacity, low extractables, and resistance to thermal and hydraulic stress. The proven performance of Millipore's filtration devices ensures uniform results every time. Fortis SL cartridges can be steamed in place up to 135 °C.

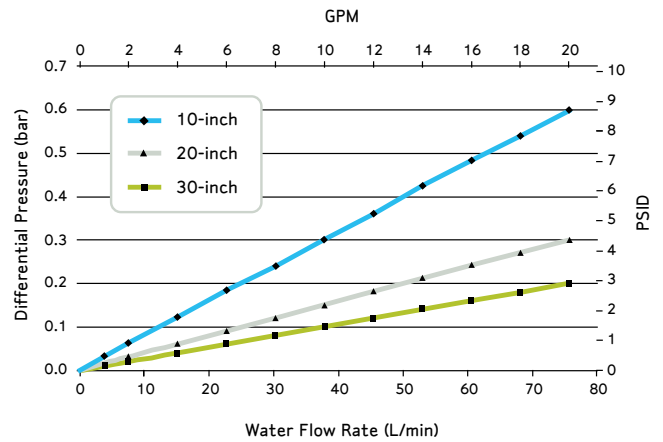
## ECONOMY

The robust design of the Fortis SL cartridge delivers superior bacterial retention and particle removal with a value to match your bulk processing needs.

## COMPLIANCE

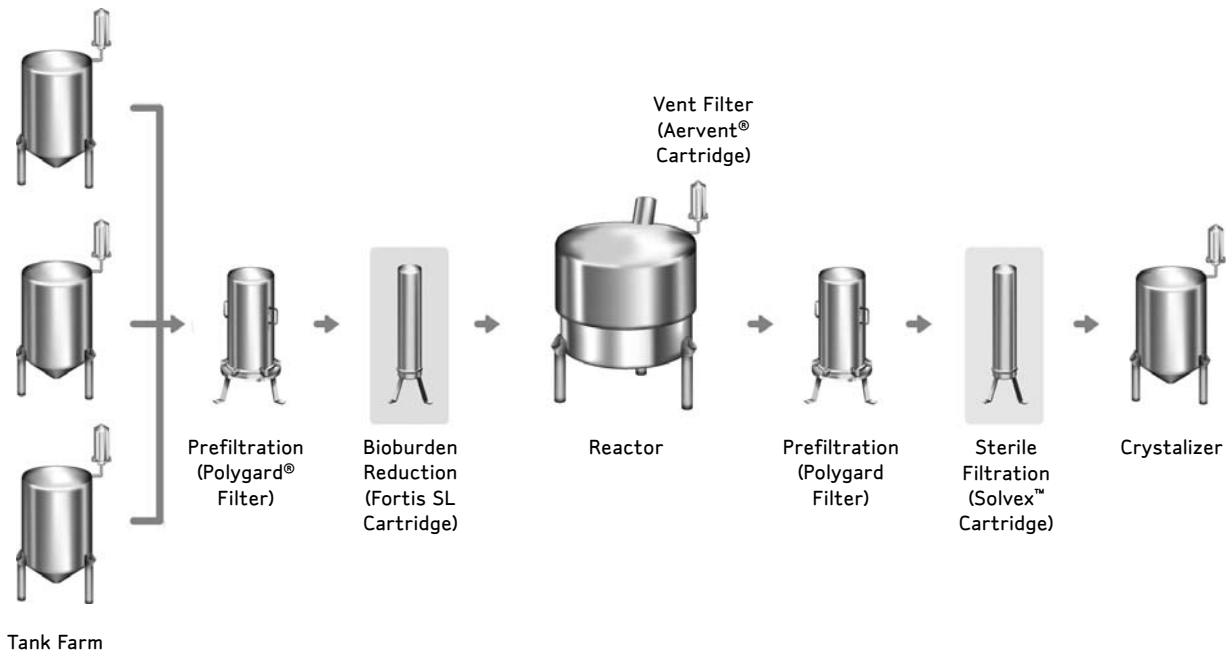
Millipore cartridges are designed and thoroughly validated for product and process quality. Each lot of Fortis SL filters is verified during manufacture and prior to release for integrity, flow rate, hydraulic stress, bacterial endotoxins and oxidizable substances.

**Figure 1. Fortis SL Cartridges Water Flow Rate vs. Differential Pressure\***



\* Typical Values for H<sub>2</sub>O

**Figure 2. Hydrophobic 0.22 µm Cartridge Filters in Antibiotic Production**



## Specifications

Per 10-inch Cartridge

### Nominal Dimensions

Outside diameter	70 mm (2.8 in.)
Maximum length:	
10-inch cartridge	319 mm (12.6 in.)
20-inch cartridge	568 mm (22.0 in.)
30-inch cartridge	816 mm (32.1 in.)
<b>Filtration Area</b>	0.52 m <sup>2</sup> (5.6 ft <sup>2</sup> )

### Materials of Construction

Filter media	PTFE membrane
Supports	Polypropylene
Structural components	Polypropylene
O-rings	EPDM, Teflon <sup>®</sup> resin-encapsulated Viton <sup>®</sup> elastomer

### Maximum Differential Pressure

Forward:	
5.5 bar (80 psid) at ambient temperature,	
1.8 bar (25 psid) at 80 °C	
Reverse:	
4.1 bar (60 psid) at ambient temperature	

### Nitrogen Diffusion

Through a 70/30 IPA/water wet membrane at ambient room at 965 mbar (14 psig) nitrogen:  
≤24 cc/min per 10-inch cartridge

### Gravimetric Extractables

After autoclaving and a 24 hour soak in 70/30 IPA water at controlled room temperature:  
≤35 mg per 10-inch cartridge

### Bacterial Endotoxin

Aqueous extraction contains < 0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.

### Bacterial Retention of Membrane

Samples were quantitatively retentive of a minimum *Brevundimonas diminuta* challenge concentration of 1 x 10<sup>7</sup> CFU/cm<sup>2</sup> using ASTM<sup>®</sup> F838 methodology.

### Sterilization

May be steam sterilized 15 times (forward) and 15 times (reverse) for 30 minutes at 135 °C

### Good Manufacturing Practices

These products are manufactured in a Millipore facility which adheres to FDA Good Manufacturing Practices.

### Non-Fiber Releasing

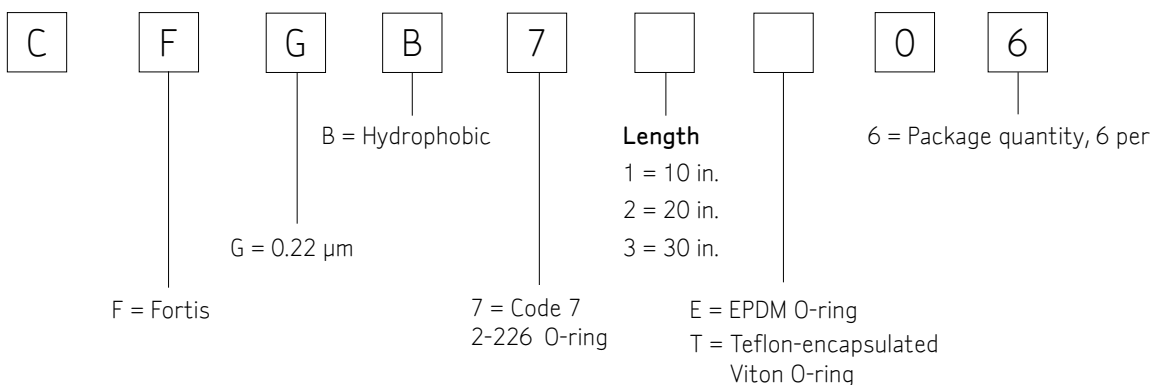
PTFE membrane meets the criteria for a "non-fiber releasing" filter as defined in 21 CFR 210.3 (b) (6).

### Component Material Toxicity

Component materials were tested and meet the criteria of USP <88> Reactivity Tests for Class VI Plastics.

## ORDERING INFORMATION

### Fortis SL PTFE 0.2 µm Filter Cartridge for Solvent Filtration



## TO PLACE AN ORDER OR RECEIVE TECHNICAL ASSISTANCE

For additional information call your nearest Millipore office:

In the U.S. and Canada, call toll-free  
**1-800-MILLIPORE (1-800-645-5476)**

In the U.S., Canada and Puerto Rico, fax orders to  
**1-800-MILLIFX (1-800-645-5439)**

Outside of North America contact your local office.

To find the office nearest you: [www.millipore.com/offices](http://www.millipore.com/offices)

Internet: [www.millipore.com](http://www.millipore.com)

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