

Solvex™ Solvent Filtration Cartridge Filters

Reliable Filtration Designed to Fit Your Needs



Optimized filtration means meeting the changing requirements of your processes and the regulations that govern them. This is why we offer you a choice. Solvex™ hydrophobic 0.2 µm solvent filtration products provide validated, robust, and cost-efficient solvent filtration. Our Solvex™ brand cartridge filters combine high-performance polytetrafluoroethylene (PTFE) membranes with a robust cartridge design to deliver validated, reliable sterile filtration and efficient particulate removal. A polymer with broad chemical and caustic compatibility, PTFE is ideal for use in the manufacture of active pharmaceutical ingredients containing methylene chloride, acetone, isopropyl alcohol, ethyl acetate and other organic solvents.

Benefits

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

Solvex™ filters meet your highest standard for sterility assurance, regulatory compliance and economy. With the quality you expect from a trusted supplier, Solvex™ brand solvent filters offer superior value through consistent and reliable performance that is guaranteed for up to 100 steam-in-place cycles. Solvex™ PTFE cartridge filters are available in 10, 20, and 30 inch sizes in code 7 O-ring adapters. Validation services and applications support are available through our BioReliance® Validation Services program.

Reliability

Solvex™ 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 our filtration devices ensures uniform results every time.

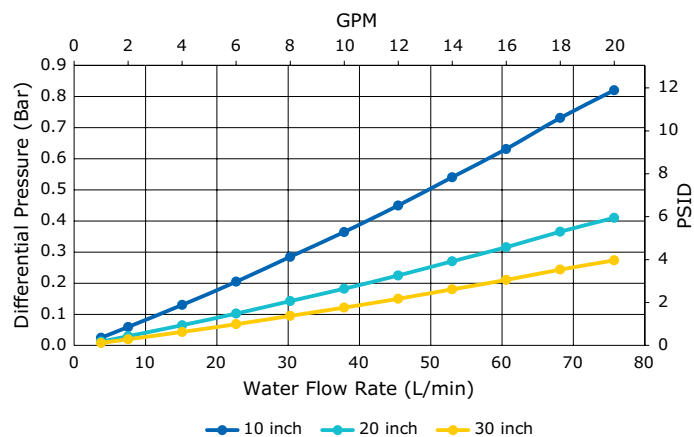
Compliance

Our cartridges are designed and thoroughly validated for product and process quality. Each lot of Solvex™ filters is verified during manufacture for flow rate and bacterial endotoxins and each cartridge is tested for integrity prior to release.

Economy

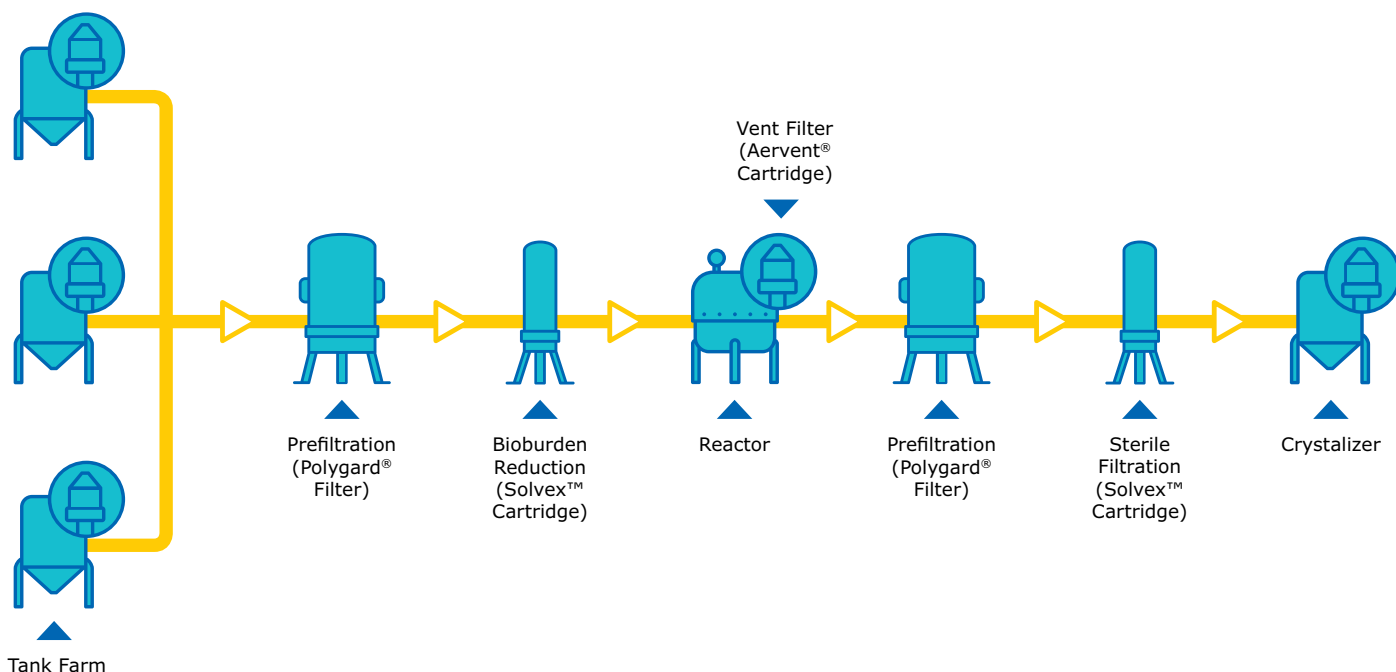
Solvex™ cartridge filters gives you the flexibility of reusing the filter multiple times, promoting an economical filtration process. Solvex™ cartridges can be steamed in place up to 100 times at temperatures of up to 135 °C.

Figure 1. Solvex™ Cartridge Water Flow Rate vs. Differential Pressure at 23 °C*



* Typical Values for H₂O.

Figure 2. Hydrophobic 0.2 µm Cartridge Filters in Antibiotic Production

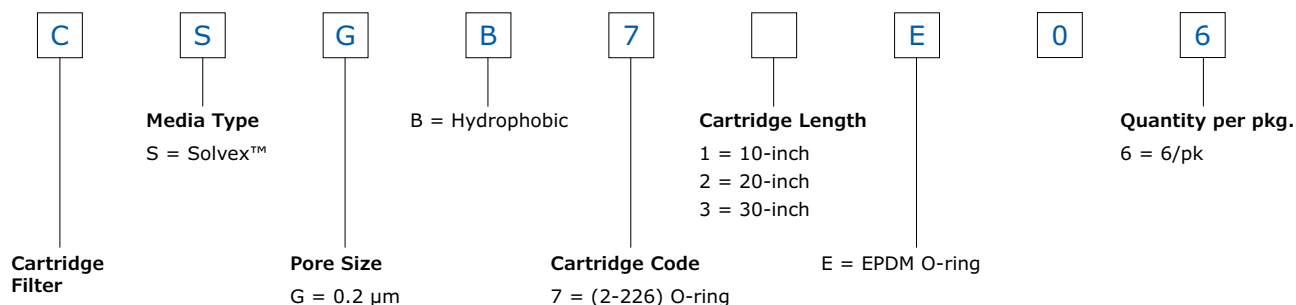


Specifications

| | |
|---|--|
| 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.) |
| Filtration Area | |
| 0.65 m ² (7.0 ft ²) | |
| Materials of Construction | |
| Filter media: | PTFE membrane |
| Supports: | Polypropylene |
| Structural components: | Polypropylene |
| O-rings: | EPDM |
| 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 |
| Diffusion at 23 °C | |
| Through a 70/30 IPA/water wet membrane at 965 mbar (14 psig) nitrogen: ≤24 cc/min per 10-inch cartridge | |
| Bubble Point at 23 °C | |
| ≥1310 mbar (19 psig) in a 70/30 IPA/water wet membrane using nitrogen | |
| 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 | |
| Samples were quantitatively retentive of a minimum <i>Brevundimonas diminuta</i> challenge concentration of 1 x 10 ⁷ CFU/cm ² using ASTM® F838 methodology. | |
| Sterilization | |
| May be steam sterilized 50 times (forward) and 50 times (reverse) for 30 minutes at 135 °C | |
| Good Manufacturing Practices | |
| These products are manufactured in a facility which adheres to 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 meet the criteria of the USP <88> Reactivity Test for Class VI Plastics. This product is non-cytotoxic per ISO® 10993-5 and USP <87> Cytotoxicity MEM Elution Test. | |

Ordering Information

Solvex™ PTFE 0.2 µm Filter Cartridge for Solvent Filtration



To place an order or receive technical assistance

In Europe, please call Customer Service:

France: 0825 045 645 Spain: 901 516 645 Option 1
Germany: 069 86798021 Switzerland: 0848 645 645
Italy: 848 845 645 United Kingdom: 0870 900 4645

For other countries across Europe, please call: +44 (0) 115 943 0840

Or visit: [MerckMillipore.com/offices](https://www.MerckMillipore.com/offices)

For Technical Service visit: [MerckMillipore.com/techservice](https://www.MerckMillipore.com/techservice)

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