Revolutionary systems for your industry

SZV Series PES – Single Layer Filter Capsules

SZV-Series PES capsules are gamma-irradiatable, easy-to-use filtration units, ideally suited for integration into single-use sterile assemblies. The hydrophilic, asymmetric Polyethersulfone (PES) membrane demonstrates exceptional throughput capacity and flow performance in liquid applications. The materials and design were carefully selected to ensure quick and reliable pre- and post-use integrity testing in critical biopharmaceutical applications. The filter capsules are available in a complete spectrum of sizes to simplify scale-up throughout each stage of the drug development process.

Application

| \triangleright | Buffers and Media | Product Sterilization | Ophthalmic |
|------------------|---------------------|-----------------------|-----------------|
| | Final Drug Product | Bio Bags | Pharmaceuticals |
| ≻ | Vaccines | Biologics | Antibiotics |
| | Scale up processing | Ultra-Pure Water | Serums |
| | | | |

Part Number: SZVS020L4H4H



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Technical Data Sheet

Popular Configuration:

| Catalog Number | Micron Rating | Inlet Connection | Outlet Connection | Vent Connection | Gamma Sterilization |
|----------------|--------------------------|---------------------|----------------------|------------------------------------|------------------------|
| SZVS020L4H4H | 0.2 μm (Single Layer) | 1/2" Hose Barb | 1/2" Hose Barb | Bleed Valve with 1/8" Hose Barb | up to 50kGy |

✤ Find the complete list of available standard inlet and outlet fittings in page 5.

Micron Rating:

Final Media: 0.2 µm PES [Sterilizing Grade Membrane]

Effective Filtration Area:

L-Size; 2.8 ft² (2,600cm²)

Materials of Construction:

Membrane: Pharmaceutical Grade PES (Polyethersulfone) Sterilizing Grade

Membrane Feature: Hydrophilic, Low Protein Binding, High Flow Rate

Media Supports: Polyester (PET)

Shell: Gamma Stable Polypropylene

Cage, Core, End Caps: Nylon

Valve O-Rings: Silicon (Standard)

Sealing: Thermally Bonded

Operating Conditions:

Maximum Forward Differential Pressure:

Liquid: 5.5 bar (80psi) at 77°F/25°C

Gas: 4.1 bar (60psi) at 77°F/25°C

Minimum Burst Pressure: 8.3 bar (120psi) at 77°F/25°C

Maximum Reverse Differential Pressure: 3.0 bar (44psi) at 68°F/20°C

Maximum Operating Temperature: 176°F/80°C

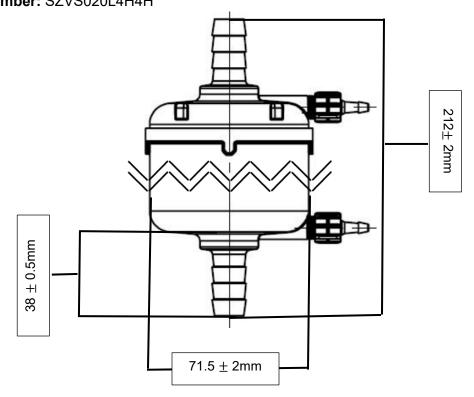








Nominal Dimension: Part Number: SZVS020L4H4H



Hold-Up Volume (Approx.):

Upstream Volume: 137 ml

Downstream Volume: 21 ml

Typical Filtered Volume:

47.5L – 89.0L

Filter Integrity:

The finished product was sampled and shown to exhibit a minimum bubble point of \geq 18 psi (1.2 bar) in 60%IPA / 40% water and \geq 50 psi (3.5 bar) in DI Water (at 22°C).

Sterilization:

Gamma Irradiation: The filters can be Gamma Sterilized up to 50kGy.

Autoclave: The filters can be autoclaved up to 10 cycles at 125°C (257°F) for 30 minutes.

Warning: The filters cannot be sterilized by steam-in-place (SIP)

Shelf Life:

The SZV capsules have a shelf life of 3 years from the date of manufacture.









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Regulatory Compliance:

| Category | Standard or Reference Test | | |
|------------------------------|---|--|--|
| Physiochemical | USP Oxidizable Substances USP <645> Conductivity USP <643> Non-Volatile Residue Total Organic Carbon (TOC) Analysis | | |
| Cleanliness | USP <85> Bacterial Endotoxin Test USP <788> Particulate Matter 21 CFR 210.72 and 2010.3 (b) (6) Fiber Shedding | | |
| Biocompatibility | ASTM F756-17 Hemolysis USP <88> (USP Class VI Plastics) Biological Reactivity Tests, In Vivo USP <87> / ISO 10993-5, In Vitro Cytotoxicity 21 CFR 177 FDA Indirect Food Additive | | |
| Bacterial Retention | Quantitative retention of 10 ⁷ CFU/cm ² <i>Brevundimonas diminuta</i> per ASTM methodology | | |
| USP Bacterial Endotoxins | A representative sample from the lot is tested to confirm that an aqueous extraction of the product contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test. | | |
| Animal-derived Components | No animal-derived material is intentionally added or used during the manufacture of PureFlo Z Series PES Capsules. | | |
| RoHS | Restriction of Hazardous Substances (RoHS 3) Directive 2015/863 | | |
| REACH | REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) Article 57, Regulation No. 1907/2006) | | |
| Traceability | For traceability and easy identification: A Certificate of Conformance is provided with each capsule. Each filter bag and box are labeled with the product part number, lot number, and identifying characteristics. Each capsule is engraved and labeled with the product part number, number, lot number, and identifying characteristics. | | |



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PROUD MEMBER Alliance for Pharmacy Compounding



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SZV- PureFlo® Z Series PES Mid-Size Capsules

Ordering Guide

| SZV[1][2][3][4][5][6] | | | | | | | | | |
|--|--|--|--|---|--|--|--|--|--|
| [1] | [2] | [3] Inlet and [4] Outlet | [5] | [6] | | | | | |
| Micron Rating [Pre-Filter/Final Filter] | Filter Size Code [Filtration Area] | Inlet and Outlet Connection | Optional Feature | Optional Vent Configuration | | | | | |
| S010 : 0.1 μm S020 : 0.2 μm ZS010 : 0.2/0.1 μm ZS020 : 0.45/0.2 μm XS010 : 0.45/0.1 μm XS020 : 0.65/0.2 μm Note: All final membranes are sterilizing grade. | H [Filtration Area: 720 cm²] S [Filtration Area: 1380 cm²] L [Filtration Area: 2600 cm²] E [Filtration Area: 3980 cm²] K [Filtration Area: 5200 cm²] | 1H : 1/8" Hose Barb 2H : 1/4" Hose Barb 3H : 3/8" Hose Barb 4H : 1/2" Hose Barb 5H : 9/16" Hose Barb MT : 1/2" Tri-Clamp TC : 1 1/2" Tri-Clamp | -FC Filling Bell (2H or 3H only) | -NO No vent near outlet -NI No vent near inlet | | | | | |

Example:

SZVXS020LTCTC

PureFlo SZV Series Capsule, Highly Asymmetric Dual Layer PES 0.65µm / 0.2µm PES membrane (Sterilizing Grade), 5.0", L-Size, Filtration Area 2,600 cm², 1.5" Tri-Clamps (Inlet/Outlet)

Part Number

Description









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Special Configuration:

Layer Option:

Micron Rating Option: **Bleed Valve Seal Option:**

- Single Layer
- Dual Layer
- 0.1 µm
- 0.2 µm •
- 0.2/0.1 µm •
- 0.45/0.2 µm •
- 0.45/0.1 µm ٠
- 0.65/0.2 µm

- Silicone
- EPDM
- Nitrile
- Viton

Inlet Fitting Option:

- 1H = 1/8" Hose Barb
- 2H = 1/4" Hose Barbs
- 3H = 3/8" Hose Barb
- 4H = 1/2" Hose Barb
- 5H = 5/8" Hose Barb
- MT = 1/2" Tri clamps
- TC = 1-1/2" Tri clamp

Outlet Fitting Option:

- 1H = 1/8" Hose Barb
- 2H = 1/4" Hose Barbs
- 3H = 3/8" Hose Barb
- 4H = 1/2" Hose Barb
- 5H = 5/8" Hose Barb
- MT = 1/2" Tri clamps •
- TC = 1-1/2" Tri clamp





