

STERYDENE

Hydrophilic PVDF membrane cartridge



- Easy integrity testable in situ
- Repeatedly steamable in situ and in autoclave
- Thermowelded construction
- EC-listed materials for Food contact
- FDA-listed materials per 21 CFR
- Bio-Safety per USP—Plastics
- Validation Guide available on request



STERYDENE filter element is designed and manufactured to satisfy and assure high quality and consistent performances in critical applications. STERYDENE cartridge includes PVDF membrane at controlled porosity and provides high efficiency in bacteria retention. The membrane is pleated with support and drainage layers in polypropylene which give high endurance versus thermal sterilization, hydraulic pulsation stress and excellent chemical compatibility. Manufacturing is completed in a controlled environment; each filter is integrity tested. STERYDENE filter element is available from 0.2 micron to 0.65 micron.

MATERIALS OF CONSTRUCTION

| | |
|----------------------------|------------------|
| Filter media | Hydrophilic PVDF |
| Upstream supports | polypropylene |
| Downstream supports | polypropylene |
| Internal Core | polypropylene |
| External Cage | polypropylene |
| End caps / Adapters | polypropylene |

FOOD-SAFETY

STERYDENE filter element materials meet (EU) regulation 10/2011 and its amendments, regulations (EC) 1935/2004 and 1895/2005.

BIO-SAFETY

Filter media and components pass USP CLASS VI Biological Reactivity and Chemical-Physical tests for USP plastics. Specific for "PH" and "PHH" grade: the filter meets USP "Water for injection" requirements for particle release and the effluent is Non-Pyrogenic per USP Bacterial Endotoxins (< 0,25 EU/ml).

QUALITY STANDARDS

Produced under a certified Quality System to guarantee traceability of manufacturing records and integrity testing results.

OPERATING CONDITIONS

| | |
|--|---|
| - max. continuous temperature | 85 °C |
| - max. cumulative time of steam sterilization | 80 hours at 125 °C with cycles of 60 minutes />100 hours at 121°C |
| - sanitization with hot water | 90 °C max |
| - sanitization with chemicals | Can be sanitized by standard chemical agents |
| - max. differential pressure | 5,0 bar at 25 °C—2,5 bar 80 °C |
| - recommended change out differential pressure | 2,0 bar at 25 °C |
| - recommended rinse up volume | 3 liters/cartridge 10" |

| CODE | ABSOLUTE FILTRATION RATING IN LIQUIDS | BACTERIAL RETENTION OF MICRO-ORGANISM >10 ¹⁰ CFU/ 10" CARTRIDGE* | ACCEPTABLE LIMIT FOR DIFFUSION FLOW TEST WITH WATER FOR 10" CARTRIDGE (ml/min) |
|------|---------------------------------------|---|--|
| TSY | 0,2 µm | Brevundimonas diminuta | ≤ 25 @ 2,3 bar |
| TST | 0,45 µm | Serratia marcescens | ≤ 16 @ 1,5 bar |
| TSK | 0,65 µm | Leuconostoc oenos | ≤ 25 @ 0,9 bar |

*as per ASTM F838

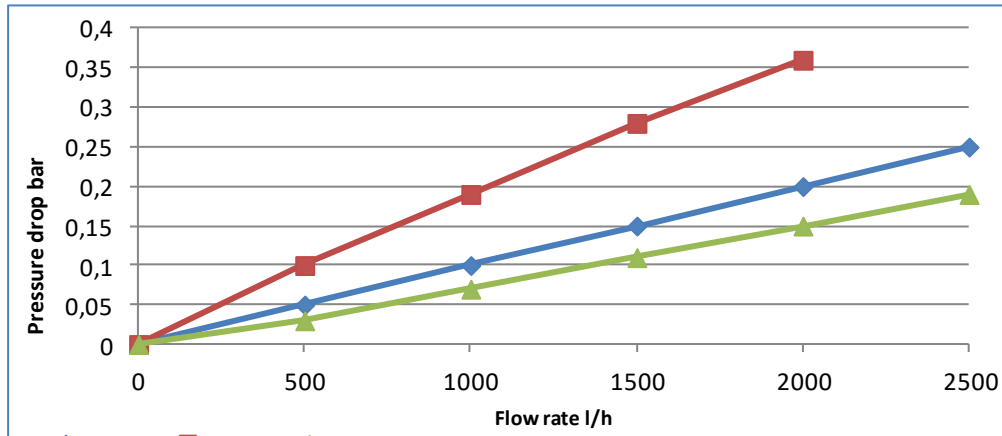
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EN Data sheet

QUALI FILTRES
SIEBEC Group

WATER FLOW RATE CURVES FOR 10" ELEMENT



STERYDENE ORDERING INFORMATION

