



Pharmastar

PSGD Type

Major Applications

Various pharmaceutical solution sterile filtration

Examples:

Eye-drop, Culture medium, Buffer, Aseptic API, Manufacturing water

Quality standards

- Manufactured in ISO 9001 certified plant
- FDA 21 CFR compliant
- USP Class VI plastic biological safety testing compliant
- Certificate of quality is attached to the product.
- 100% integrity tested by diffusion flow test
- Traceability by lot number and serial number

Features

- Integrity test factors correlated with microbial removal performance
- Multi-layered structure using high removal efficiency polypropylene on the primary side and asymmetric hydrophilic PES membrane on the secondary side
- Use of highly durable materials

Advantages

- Sterilization of chemicals is possible
- Excellent flow rate even in chemical filtration with a lot of colloidal impurities and precipitates
- No hydrophilization treatment required
- High differential pressure resistance (0.63MPa)

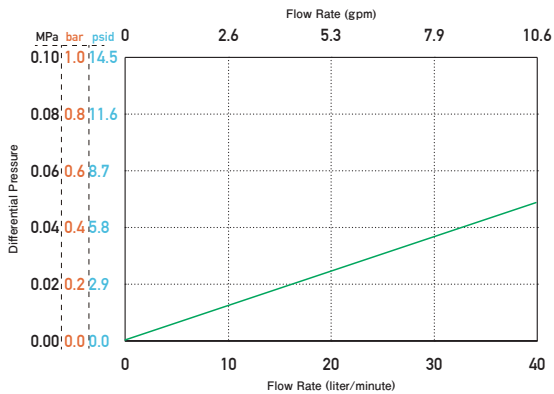
Specifications

Grades	002
Micron Ratings	0.2μm
E.F.A.	0.66m ² /250mm
Media	Pre-layer: Polypropylene / Final layer: Polyestersulfone (PES) membrane
Materials	Core/Cage/Support End Cap
	Polypropylene Polypropylene
Maximum ΔP	0.63MPa at 20°C (91psi at 68°F)
Maximum Operating Temp	80°C (176°F)
Dimensions	Length O.D. I. D.
	125 / 250 / 500 / 750 mm 70.0mm 26.9 (for 3, 4) / 29.5 (for 6, 7) mm
Bubble Point	≥365kPa (Pure water)
Diffusion flow test	≤17ml/min (per 250mm, Pure water 0.28MPa at 20°C(41psi at 68°F))
Inline steam sterilization	135 °C (275°F) x 30 minutes x 30 cycles

*If you need further information on specifications (length, end cap type, etc.), please contact us.

Differential Pressure vs Flow Rate

Fluid: Refined Water 20°C (68°F) / Cartridge Length: 250mm



Sterilization performance

Grades	Biological Indicator	LRV*
002	<i>Brevundimonas diminuta</i> (ATCC 19146)	>7

*LRV represents Log Reduction Value (Refer to JIS K3835)
*Challenge bacteria count is more than 1×10^7 CFU/cm².

Validation items

Items	Evaluation criteria	Items	Evaluation criteria
Bacteria Challenge	The removal performance of <i>Brevundimonas diminuta</i> (ATCC 19146) in a 250mm cartridge is 10^7 CFU/cm ² or more, and the filtrate is sterile.	Potassium permanganate consumption	Meets the requirements of the USP Oxidizable Substance Test by flushing with at least 1,000 mL of ultrapure water after autoclaving
Durability for steam	Maintains integrity correlated with microbial capture performance under conditions of 135 °C x 30 minutes x 30 cycles	Fiber release	Meets the requirements of non fiber release which defined in 21 CFR210.3(b)(6)
Endotoxin (LAL)	Extraction volume with water is less than 0.25 EU/mL and complies with USP <85> requirements.	Particle component flow out	Meets the requirements for particle contained in injection solution by the test method based on USP <788>
Evaporation residues	Less than 10 mg of evaporation residue per 250 mm cartridge after 24 hours in ultrapure water following autoclave sterilization	Filter/component toxicity	USP <88> Biological Reactivity Tests For Class VI Plastics compliant
TOC	After autoclave sterilization, flushing with 10,000 mL or more of ultrapure water has a TOC of less than 0.5 mg / L and meets the requirements of USP <643>.	Cytotoxicity	Meets the requirements of the USP <87> Biological Reactivity Tests, In Vitro
Conductivity	After autoclave sterilization, flushing with 10,000 mL or more of ultrapure water. Conductivity is less than 1.1 μS / cm and meets USP <645> requirements		

*Please refer to the Validation Guide for detailed testing information.

Ordering Information

Nominal Length	Product Type	Micron Rating	O-Ring	End Cap Code	Packaging Code
250 L	-PSGD-	002	S	7	B
125 = 125mm 250 = 250mm 500 = 500mm 750 = 750mm		0.2μm	Silicone	3 = 2-222 O-Ring + Fin 4 = 2-222 O-Ring 6 = 2-226 O-Ring 7 = 2-226 O-Ring + Fin	A = 1pc B = 6pcs C = 10pcs F = 25pcs

* Packaging code F is only available for 125/250mm cartridge.

End Cap Code

Code 3

Code 4

Code 6

Code 7



*The contents of the catalog are subject to change without notice.

*The performance data listed in the catalog are Typical values obtained under specific conditions based on our tests.

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Manufacturing is based on our Quality Management Systems that meet ISO9001 standards.

Scope
Design, Development, manufacture, and sales of filter cartridges, housings and filtration equipment.



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