


Pharmastar

PSG Type

Major Applications

Sterilization of various chemicals

Low to medium viscosity chemicals,
Eye-drop, Disinfectant, Drinks,
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 test
- Traceability by lot number and serial number

Features

- Integrity test factors correlate with microbial removal performance
- Hydrophilic asymmetric polyether sulfone membranes are used
- Use of highly durable materials

Advantages

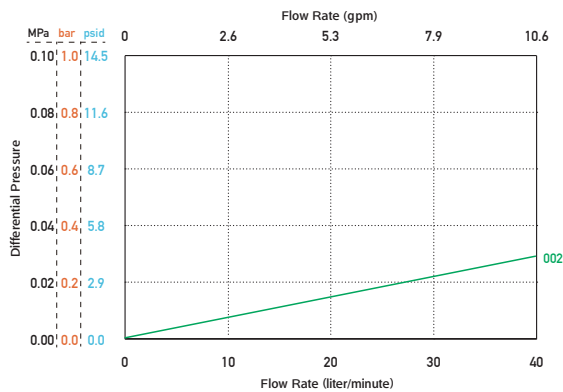
- Sterilization of chemicals is achieved
- Low pressure drop and excellent flow rate
- No hydrophilization treatment required
- High differential pressure resistance (0.63MPa)

Specifications

Grades	002
Micron Ratings (μm)	0.2
E.F.A.	0.77m ² /250mm
Media	Polyethersulfone (PES) Membrane
Materials	Polypropylene
Core/Cage/Support	Polypropylene
End Cap	Polypropylene
Maximum ΔP	0.63MPa at 20°C (91psi at 68°F)
Maximum Operating Temp	80°C (176°F)
Length	125 / 250 / 500 / 750 mm
Dimensions	O.D.
	70.0mm
	I. D.
	26.9 (for 3, 4) / 29.5 (for 6, 7) mm
Bubble Point	$\geq 365\text{kPa}$ (Pure water)
Diffusion	$\leq 25\text{ml/min}$ (per 250mm, Pure water 0.28MPa)
Hot water sterilization	90 °C (194°F) x 30 minutes x 150 cycles *Code 6, 7 only
Inline steam sterilization	135 °C (275°F) x 30 minutes x 30 cycles

Differential Pressure vs Flow Rate

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



Microbial removal performance

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

*LRV represents Log Reduction Value (Refer to JIS K3835)

*Bacterial challenge level is more than 10⁷CFU/cm².

Validation items

Items	Evaluation criteria
Bacteria Challenge	A challenge concentration of at least 10 ⁷ CFU of <i>Brevundimonas diminuta</i> (ATCC19146) per 1cm ² of effective filtration area, resulting in no passage of the challenge microorganism.
Durability for steam	Maintains integrity correlated with microbial capture performance under conditions of 135 °C x 30 minutes x 30 cycles
Endotoxin (LAL)	Extraction volume with water is less than 0.25 EU/mL and complies with USP (85) requirements.
Evaporation residues	Less than 5 mg of evaporation residue per 250 mm cartridge after 24 hours in ultrapure water following autoclave sterilization
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) .

Items	Evaluation criteria
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
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
Fiber release	Meets the requirements of non fiber release which defined in 21 CFR210.3(b)(6)
Particle component flow out	Meets the requirements for particle contained in njection solution by the test method based on USP (788)
Filter/component toxicity	USP (88) Biological Reactivity Tests For Class VI Plastics compliant
Cytotoxicity	Meets the requirements of the USP (87) Biological Reactivity Tests, In Vitro

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

Ordering Information

Length	Product Type	Micron Rating	O-Ring	End Cap Code
2 5 0 L	-PSG-	002	S	7
125 = 125mm 250 = 250mm 500 = 500mm 750 = 750mm		002 = 0.2 μm	Silicone	3 = 2-222 O-Ring + Fin 4 = 2-222 O-Ring 6 = 2-226 O-Ring 7 = 2-226 O-Ring + Fin

* Packing quantity
125 and 250L: 6 or 25 pcs
500 and 750L: 6 or 10 pcs

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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MS CM009

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