ROKI TECHNO

Surface (Membrane)

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 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)

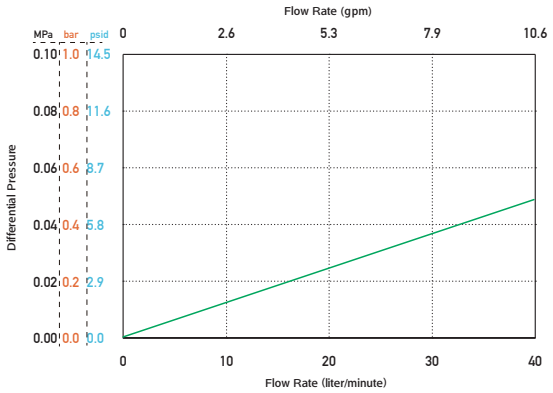
Specifications

Grades		002
Micron Ratings		0.2 μm
E.F.A.		0.66m²/250mm
Materials	Media	Pre-layer: Polypropylene / Final layer: Polyestersulfone (PES) membrane
	Core/Cage/Support	Polypropylene
	End Cap	Polypropylene
Maximum ΔP		0.63MPa at 20℃ (91psi at 68°F)
Maximum Operating Temp		80℃ (176°F)
Dimensions	Length	125／250／500／750 mm
	O.D.	70.0mm
	I.D.	26.9 (for 3, 4)／29.5 (for 6, 7) mm
Bubble Point		≧365kPa (Pure water)
Diffusion		≦17ml/min (per 250mm, Pure water 0.28MPa at 20℃(41psi at 68℉))
Inline steam sterilization		135 ℃ (275°F) x 30 minutes x 30 cycles

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

Differential Pressure vs Flow Rate

Fluid: Refined Water 20℃ (68℉) / Cartridge Length: 250mm



Microbial removal performance

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

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

*Bacterial challenge level is more than 1×10^7CFU/cm².

Validation items

Items	Evaluation criteria
Bacteria Challenge	A challenge concentration of at least 10^7CFU of *Brevundimonas diminuta*(ATCC19146) per 1cm² 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 ℃ 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 10 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〉.
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

Items	Evaluation criteria
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 injection 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
250L	-PSGD-	002	S	7
▼		▼	▼	▼
125 = 125mm 250 = 250mm 500 = 500mm 750 = 750mm		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.

ISO 9001 JQA-QMA16323

JAB MS CM009

6th Issue
PGSD210602LE