ROKI TECHNO

Surface (Membrane)

CERTAIN-PORE

ACES Type

Major Applications

- Water-based pharmaceutical liquids clarification
- Reduction of microorganisms and bacteria in various pharmaceutical liquids
- Pre-filter for filtration and sterilization of water-based pharmaceutical liquids

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 test by diffusion test
- Traceability by lot number

Features

- Asymmetric hydrophilic polyethersulfone membrane

Advantages

- Low pressure drop and excellent flow rate
- No hydrophilization treatment required

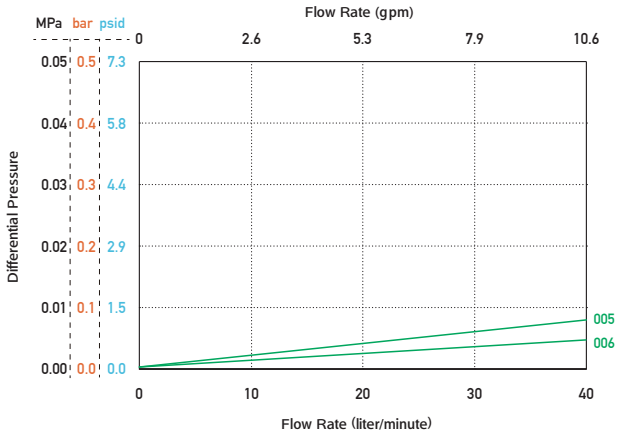
Specifications

Grades		005	006
Micron Ratings (μm)		0.45	0.65
E.F.A.		0.77m²/250mm	
Materials	Media	Polyethersulfone (PES) Membrane	
	Core/Cage/Support	Polypropylene	
	End Cap	Polypropylene	
Maximum ΔP		0.49MPa at 40℃ (71psi at 104°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	
Available sterilization methods		Inline steam, Autoclave	
Diffusion		≦25ml/min (per 250mm, Pure water 0.15MPa)	≦15ml/min (per 250mm, Pure water 0.10MPa)
Inline steam sterilization		135 ℃ (275°F) x 30 minutes x 30 cycles (for 3, 4) 135 ℃ (275°F) x 30 minutes x 50 cycles (for 6, 7)	
Hot water sterilization		90 ℃ (194°F) x 30 minutes x 150 cycles *Applicable to only code 6, 7 with Silicone O-rings.	

*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※
005	*Lactobacillus brevis* (IFO3345)	>7
006	*Lactobacillus brevis* (IFO3345)	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	ACES-005 and ACES-006 have the following retention capability of *Lactobacillus brevis* (IFO No.3345) challenge.
Durability for steam	Maintains integrity correlated with microbial capture performance under given conditions
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

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
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

5 0 0 L

- 125 = 125mm
- 250 = 250mm
- 500 = 500mm
- 750 = 750mm

Product Type

-ACES-

Micron Rating

0 0 5

- 005 = 0.45 μm
- 006= 0.65 μm

O-Ring

S

- Silicone

End Cap Code

7

- 3 = 2-222 O-Ring + Fin
- 4 = 2-222 O-Ring
- 6 = 2-226 O-Ring
- 7 = 2-226 O-Ring + Fin

Packaging Code

B

- A = 1pc
- B = 6pcs
- C = 10pcs
- F = 25pcs

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

ACES200723LE