



# WACTcap

Pharmastar

## PSGG Type

### Major Applications

- Aseptic filtration of culture media
- Bioburden reduction of buffers
- Bioburden reduction of stored intermediates
- Final Filtration Sterilization

### 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 and serial number

### Features

- Integrity test factors correlate with microbial capture performance
- Asymmetric hydrophilic polyethersulfone membrane
- Use of component materials durable to 50 kGy of gamma radiation
- Filter is disposable, built into a polypropylene capsule
- Valve mechanism for vent and drain

### Advantages

- Capable of filter sterilization of chemicals
- Low pressure drop and excellent flow rate
- Can be incorporated into single-use assemblies
- Flexibility for filtration lines from development to production
- Easy vent and drain operation in closed system lines

## Specifications




Capsule Type	502	504
Built-in filter length	50	100
Micron Ratings ( $\mu\text{m}$ )	0.2	
E.F.A. ( $\text{m}^2$ )	0.084	0.174
Media	Polyethersulfone (PES) Membrane	
Support	Polypropylene	
Materials Core/Cage/End Cap	Polypropylene	
Shell	Polypropylene	
O-Ring	Silicone	
Bubble Point	$\geq 375\text{kPa}$ (Pure water)	
Diffusion (Pure water 0.33MPa)	$\leq 3\text{mL/min}$	$\leq 7\text{mL/min}$
Maximum $\Delta P$	0.55MPa at 25°C (79psi at 77°F), 0.1MPa at 80°C (14psi at 176°F)	
Gamma-ray durability	50kGy	

## Validation items (All validations were performed with filters after 50 kGy of gamma radiation)

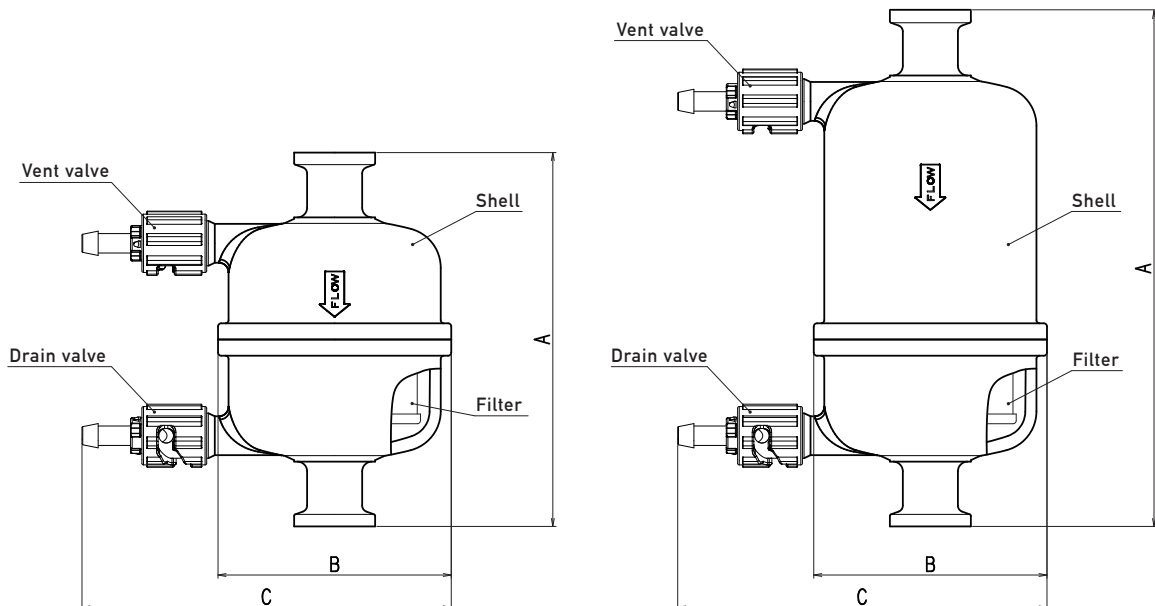
Items	Evaluation criteria
Bacteria Challenge	A challenge concentration of at least $10^7$ CFU of <i>Brevundimonas diminuta</i> (ATCC19146) per 1cm <sup>2</sup> of effective filtration area, resulting in no passage of the challenge microorganism.
Endotoxin (LAL)	Extraction volume with water is less than 0.25 EU/mL and complies with USP <85> requirements.
TOC	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	Flushing with 25,000 mL or more of ultrapure water. Conductivity is less than 1.1 $\mu$ S / cm and meets USP <645> requirements
Fiber release	Meets the requirements of non fiber release which defined in 21 CFR210.3(b)(6)
Particle component outflow	Meets the requirements for the particle contained in the injection solution according to 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.

## Code and Dimension

Connection shape code	IN/OUT (shape selection)		Vent / Drain
	F	H	None
	Standard 3/4" Ferrule	1/2" Single-hose barb	1/4" Single-hose barb
Shape			

## Dimension (mm)



Capsule type	502			504		
Connection shape code	FF	HH	FH	FF	HH	FH
A	115	119	117	159	163	161
B	72	72	72	72	72	72
C (Valve closed)	114	114	114	114	114	114
C (Valve open)	118	118	118	118	118	118

## Microbial removal performance

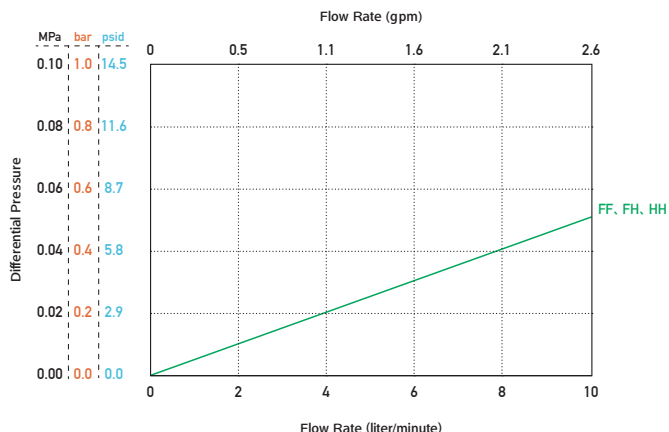
Biological Indicator	LRV*
<i>Brevundimonas diminuta</i> (ATCC19146)	>7

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

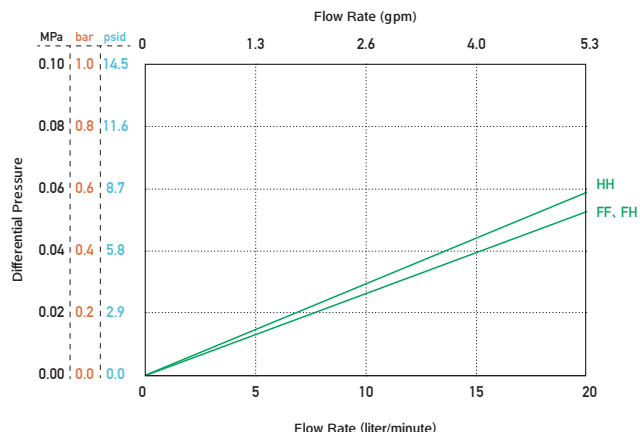
\*Bacterial challenge level is more than  $10^7$ CFU/cm<sup>2</sup>.

## Differential Pressure vs Flow Rate

Capsule Type: 502  
Fluid: Refined Water 20°C (68°F)



Capsule Type: 504  
Fluid: Refined Water 20°C (68°F)



## Liquid volume in capsule filter

Capsule Type	at full capacity (mL)	Liquid loss volume (mL)
502 (mL)	99	33
504 (mL)	169	52

\*Liquid volume verified by connection shape code FF

\*Liquid loss is measured after 1 minute of air blow at 50 kPa

## Packaging

Packaging	Protective caps on IN/OUT, vent and drain sections Double-wrapped in clean PE bags
Standard Box Quantity	3 or 6 in a corrugated cardboard outer layer box
When shipped	Unsterilized

\*Orders are accepted in increments of 3 or 6 bottles.

## Ordering Information

Capsule Type	Filter Product Type	Micron Rating	Flow Type	Connection Shape Code
5 0 2 G	-PSGG-	0 0 2	-I	F F
▼		▼	▼	▼
502 = 2 inch 504 = 4 inch		002 = 0.2 μm	I = I Flow	IN Side OUT Side
				F = Ferrule H = Single-hose barb
				F = Ferrule H = Single-hose barb

\*Connection shape code HF is not selectable.

\*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.

# ROKI GROUP International Pte. Ltd.

6-20-12, Minami-Oi, Shinagawa-ku Tokyo, 140-0013 Japan

TEL: +81-3-5764-1131 FAX: +81-3-5764-0681

[www.rokiglobal.com](http://www.rokiglobal.com)

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.



1st Issue  
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