Bringing Technology to the World

CERTAIN - PORE CES filter cartridge Validation Guide

ROKI TECHNO

CONTENTS

1. Overview

This validation guide is created to help the customer understand the fundamentals of the ” CERTAIN-PORE CES” filter cartridges.
This document can be used as reference material when customers set up and manage the filtration process. It provides necessary information on filter cartridges.

※**The performance data listed in this validation guide are typical values obtained under specific conditions based on our tests, not guaranteed values.**

◆Product Type and Micron Rating

Product Type (Grade)	Micron Rating
CES-002	0.20μm
CES-005	0.45μm
CES-006	0.65μm

If you need information on this validation guide, please contact below.

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2. Test Items

2-1. Bacterial Challenge Test

【Summary】

This test confirms the filter's sterilization performance when filtering certain type of bacteria in liquid.

【Criteria】

Confirm the LRV (Log Reduction Value) in the Bacterial Challenge Test.
LRV Standard : LRV>7(CES-002, 005), LRV≧7(CES-006)

【Sample】

250L-CES-002S7, 250L-CES-005S7, 250L-CES-006S7

【Method】

<Conditions>

[Biological Indicator]

・250L-CES-002 Brevundimonas diminuta (IFO 14213)
・250L-CES-005 Lactobacillus brevis (IFO 3345)
・250L-CES-006 Lactobacillus brevis (IFO 3345)

[Filtration Conditions]

・ Filtration pressure : 0.1MPa【14.5psi/1.0bar】

[Test Solution]

・ Cultivation medium : Saline Lactose Broth
・ Cultivation temperature/Time : 30℃【86°F】, 24 hours
・ Bacterial concentration : 10^7cfu/cm^2 or more

[Measuring the number of bacteria in the Filtrate]

・ Measuring filter : 0.22μm
・ Medium / Incubation temperature / Time : SCD agar medium / 30℃【86°F】/ 2 days

[LRV Calculation Method]

$$LRV = \mathrm{Log}_{10} \frac{\text{(The number of bacteria challenged to the filter cartridge)}}{\text{(The number of bacteria in the filtrate)}}$$

※LRV represents the Log Reduction Value (see JIS K3835)

◆**Integrity test**

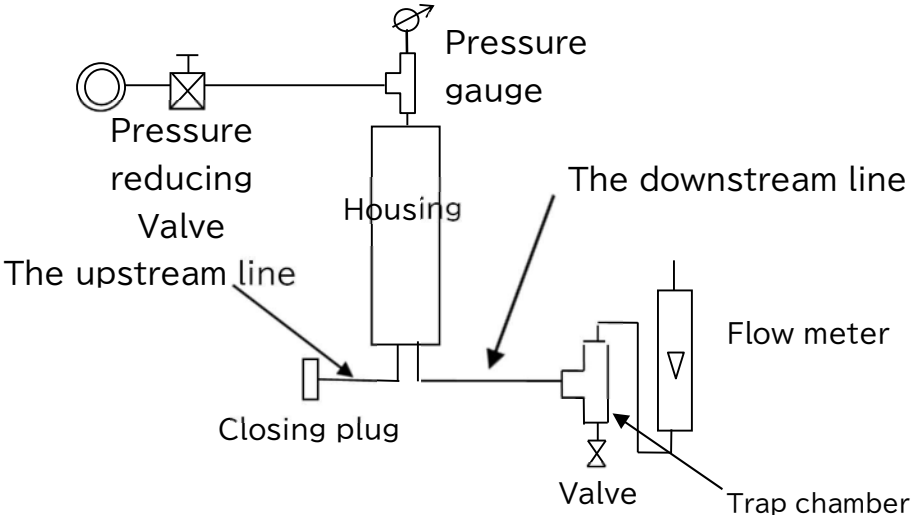
The definition of a sterile filter is its ability to capture Brevundimonas diminuta and Lactobacillus brevis as Indicator bacteria with LRV>7(CES-002, 005), LRV≧7(CES-006) performance.

◆**Diffusion test (DF test)**

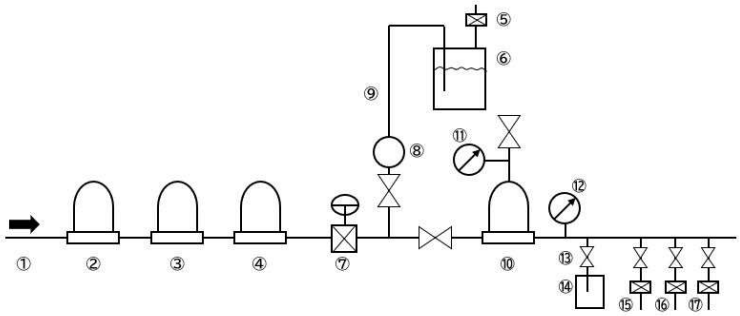
Set a wetted filter cartridge in the filter housing and apply air from the upstream line at a pressure of 0.20MPa【2. 90psi/2.0bar】(CES-002) ,0.15MPa【21.8psi/1.5bar】(CES-005) and 0.10MPa【14.5psi/1.0bar】(CES-006).

For DF test, measure the flow rate as air flows through the wetted membrane to the downstream line.

<Schematic DF Test Line >



<Schematic Bacteria Challenge Test Line>



①Water
②Pre-Filter cartridge
③Activated carbon filter cartridge
④Sterilization filter cartridge
⑤Airvent
⑥Bacterial culture tank
⑦Flor rate control valve
⑧Bacterial culture flow rate control
⑨Plumbing for bacterial culture injection
⑩Filter element for test
⑪Pressure gauge
⑫Pressure gauge
⑬Plumbing for diffusion
⑭Measuring instruments
⑮Filter cartridge for test(Purity)
⑯Filter cartridge for test(Challenge)
⑰Filter cartridge for test(Chase)

【Results】

Catalog No.	250L-CES-002			Micron Rating	0.20μm
Indicator	Brevundimonas diminuta (IFO 14213)				
No.	DF Standard (mL/min)	DF (mL/min)	Number of bacteria(CFU)		LRV ※3
			Bacterial challenge level※1	Challenge ※2	
1	≦20	10	2.4×10^{11}	0	>11.4
2	≦20	10	2.8×10^{11}	0	>11.5
3	≦20	10	7.4×10^{11}	0	>11.9

Catalog No.	250L-CES-005			Micron Rating	0.45μm
Indicator	Lactobacillus brevis (IFO 3345)				
No.	DF Standard (mL/min)	DF (mL/min)	Number of bacteria(CFU)		LRV ※3
			Bacterial challenge level ※1	Challenge ※2	
1	≦25	10	1.4×10^{11}	0	>11.1
2	≦25	10	8.8×10^{11}	0	>11.9
3	≦25	10	1.1×10^{12}	0	>12.0

Catalog No.	250L-CES-006			Micron Rating	0.65μm
Indicator	Lactobacillus brevis (IFO 3345)				
No.	DF Standard (mL/min)	DF (mL/min)	Number of bacteria(CFU)		LRV ※3
			Bacterial challenge level ※1	Challenge ※2	
1	≦15	5	2.2×10^{11}	7.5×10^{3}	8.7
2	≦15	7	9.0×10^{11}	5.0×10^{3}	10.3
3	≦15	5	2.6×10^{12}	4.9×10^{2}	9.1

※1:Total number of bacteria tested per 250mm type cartridges

※2:The number of bacteria passed in the filtrate

※3:LRV=$\log_{10}$(Bacterial challenge level)/(number of fungi in filtration solution)

【Conclusion】

Bacterial Challenge Test (liquid) confirmed filtration sterilization performance of CES filter cartridge with LRV> 7(CES-002, 005) and LRV≧7(CES-006) is satisfied.

2-2. Differential Pressure Resistance Test

【Summary】

This test confirms the durability of filter cartridges when repeatedly subjected to pressure.

【Criteria】

The appearance of the filter cartridge remains unchanged and integrity is maintained.

Appearance standard : Visual check for deformation and damage that may impair the merchantability.

Standard value (DF) : ≦20 mL/min(CES-002), ≦25 mL/min(CES-005), ≦15 mL/min(CES-006)

【Sample】

250L-CES-002S7, 250L-CES-005S7, 250L-CES-006S7

【Method】

<Pressurization Test Conditions>

- Testing pressure : Positive pressure 0.55MPa【79.8psid/5.5bar】,40℃【104°F】
  0.25MPa【36.3psid/2.5bar】,80℃【176°F】
- Pulse pressure : 100 cycles

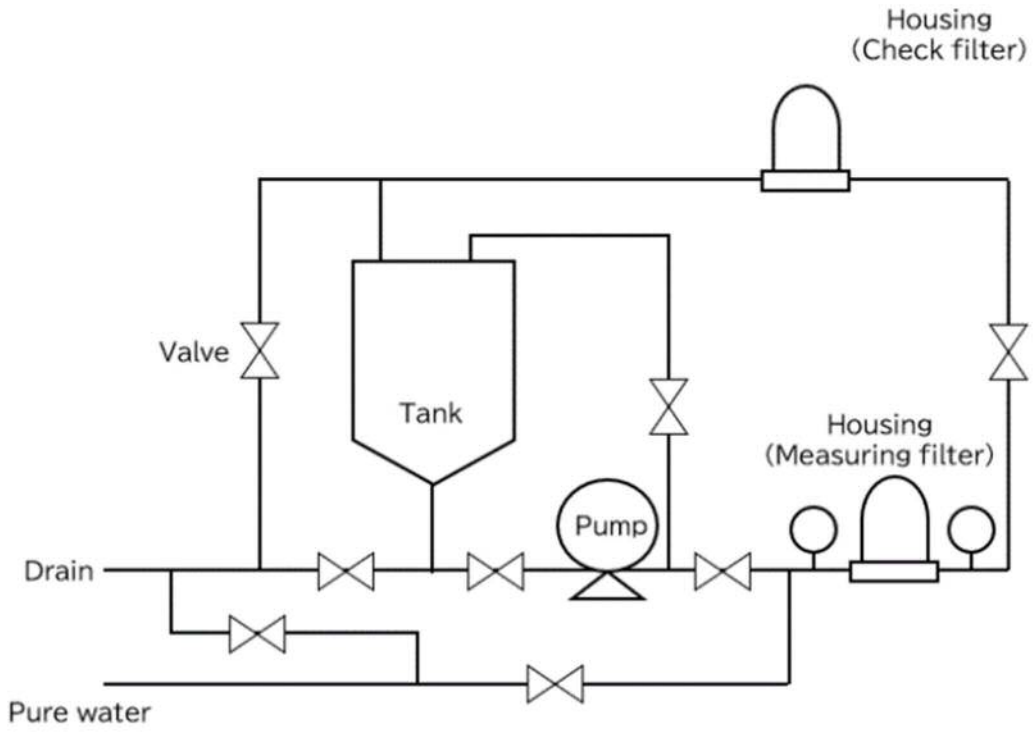
<Integrity Test Conditions>

- Measurement solution : Pure Water
- Measured pressure : 0.20MPa【29.0psi/2.0bar】(CES-002)
  0.15MPa【21.8psi/1.5bar】(CES-005)
  0.10MPa【14.5psi/1.0bar】(CES-006)

<Procedure>

① Put pure water into the tank and adjust the temperature.
② Run the pump and flow pure water through the product while checking the flow meter.
③ Fill the tank with dust to clog the filter until the test pressure is reached.
④ After continuous 100 pulses of "water flow 10 sec + stop 5 sec", check the integrity (DF) of the filter cartridge.

<Schematic Differential Pressure Resistance Test Line>



【Results】

Catalog. No.	250L-CES-002			Micron Rating	0.20μm
Temperature 【℃,°F】	Differential pressure			No.	DF(mL/min)
	(MPa)	(psid)	(bar)		Before / After
40℃,104°F	0.55	79.8	5.5	1	12 / 1
				2	10 / 3
80℃,176°F	0.25	36.3	2.5	3	10 / 1
				4	8 / 6

※DF standard value: ≦20 mL/min, Measurement solution: Pure Water, Measurement pressure: 0.20MPa【29.0psi/2.0bar】

Catalog. No.	250L-CES-005			Micron Rating	0.45μm	
Temperature【℃,˚F】	Differential pressure			No.	DF(mL/min)	
	(MPa)	(psid)	(bar)		Before	After
40℃,104˚F	0. 55	79.8	5.5	1	8	2
				2	8	3
80℃,176˚F	0.25	36.3	2.5	3	6	3
				4	6	2

※DF standard value: ≦25 mL/min, Measurement solution: Pure Water, Measurement pressure: 0.15MPa【21.8psi/1.5bar】

Catalog. No.	250L-CES-006			Micron Rating	0.65μm	
Temperature【℃,˚F】	Differential pressure			No.	DF(mL/min)	
	(MPa)	(psid)	(bar)		Before	After
40℃,104˚F	0. 55	79.8	5.5	1	4	<1
				2	5	<1
80℃,176˚F	0.25	36.3	2.5	3	4	2
				4	4	4

※DF standard value: ≦15 mL/min, Measurement solution: Pure Water, Measurement pressure: 0.10MPa【14.5psi/1.0bar】

【Conclusion】

Differential Pressure Resistance Test confirmed that the appearance of CES filter cartridge is not changed. The integrity of the filter cartridge is maintained.

2-3. Steam Resistance Test

【Summary】

This test confirms the durability of the filter cartridge when repeatedly subjected to in-line steam.

【Criteria】

The appearance of the filter cartridge remains unchanged and integrity is maintained.

Appearance standard: Visual check for deformation, color change and damage that may impair merchantability.

Standard value (DF) : ≦20 mL/min(CES-002), ≦25 mL/min(CES-005), ≦15 mL/min(CES-006)

【Sample】

250L-CES-002S7, 250L-CES-005S7, 250L-CES-006S7

【Method】

<Conditions>

- Steam temperature : 135℃【275°F】
- Heating time : 30 min
- Cooling time : 15 min(air cooling)
- Number of cycles : 50 cycles

<Integrity Test Conditions>

- Measurement solution : Pure Water
- Measured pressure : 0.20MPa【29.0psi/2.0bar】(CES-002)
  0.15MPa【21.8psi/1.5bar】(CES-005)
  0.10MPa【14.5psi/1.0bar】(CES-006)

<Procedure>

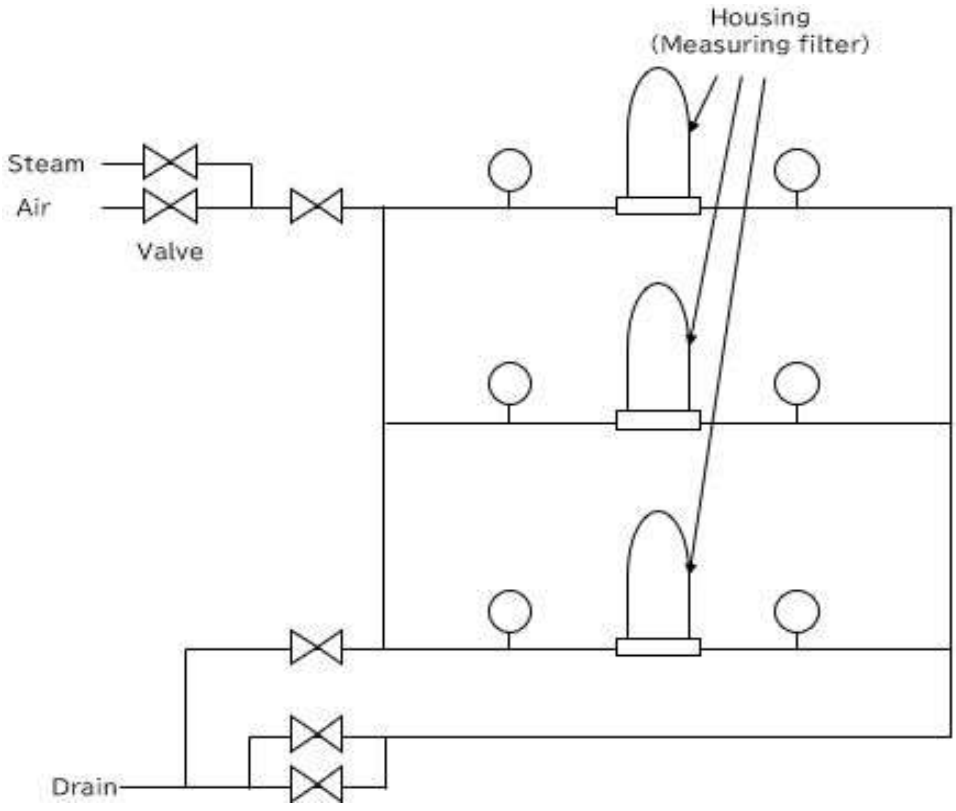
① Steam is gradually supplied from the upstream side of the filter housing and heated to a predetermined attainable temperature. At this time, the maximum differential pressure should not exceed 0.05MPa【7.3psi/0.5bar】during the boosting process.

② After the specified heating time has elapsed, the steam supply is shut off and air at room temperature flows through to cool the filter cartridge.

③ The above steam heating and cooling is one cycle, and the specified cycle is repeated in the positive and back pressure directions.

④ Check the integrity (DF) of filter cartridges after ③.

<Schematic Steam Resistance Test Line>



【Results】

Catalog. No.	250L-CES-002S7	Micron Rating	0.20μm
No.	DF(mL/min)		
	Before	After	
1	10	10	
2	10	10	
3	11	10	

※DF standard value: ≦20mL/min, Measurement solution: Pure Water, Measurement pressure: 0.20MPa【29.0psi/2.0bar 】

Catalog. No.	250L-CES-005S7	Micron Rating	0.45μm
No.	DF(mL/min)		
	Before	After	
1	8	10	
2	8	8	
3	8	9	

※DF standard value: ≦25 mL/min, Measurement solution: Pure Water, Measurement pressure: 0.15MPa【21.8psi/1.5bar】

Catalog. No.	250L-CES-006S7	Micron Rating	0.65μm
No.	DF(mL/min)		
	Before	After	
1	5	2	
2	5	1	
3	6	2	

※DF standard value: ≦15 mL/min, Measurement solution: Pure Water, Measurement pressure: 0.10MPa【14.5psi/1.0bar】

【Conclusion】

Steam Resistance Test confirmed that the appearance of CES filter cartridge was not changed. The filter performance of the filter cartridge was maintained.

2-4. Hot Water Resistance Test

【Summary】

This test confirms the integrity of the filter cartridge when hot and cold water is applied.

【Criteria】

The appearance of the filter cartridge remains unchanged and integrity is maintained.

Appearance standard ： Visual check for deformation, color change and damage that may impair merchantability.

Standard value (DF) ： ≦20 mL/min(CES-002), ≦25 mL/min(CES-005), ≦15 mL/min(CES-006)

・ Measurement solution ： Pure Water

【Sample】

250L-CES-002S7, 250L-CES-005S7, 250L-CES-006S7

【Method】

＜Conditions＞

・ Temperature(hot water) ： 90℃【194°F】
・ Heating time(hot water) ： 30 min
・ Temperature(cold water) ： Room temperature
・ Cooling time(cold water) ： 10min
・ Number of cycles ： 150 cycles

＜Integrity Test Conditions＞

・ Measurement solution ： Pure Water
・ Measured pressure ： 0.20MPa【29.0psi/2.0bar】(CES-002)
0.15MPa【21. 8psi/1.5bar】(CES-005)
0.10MPa【14. 5psi/1.0bar】(CES-006)

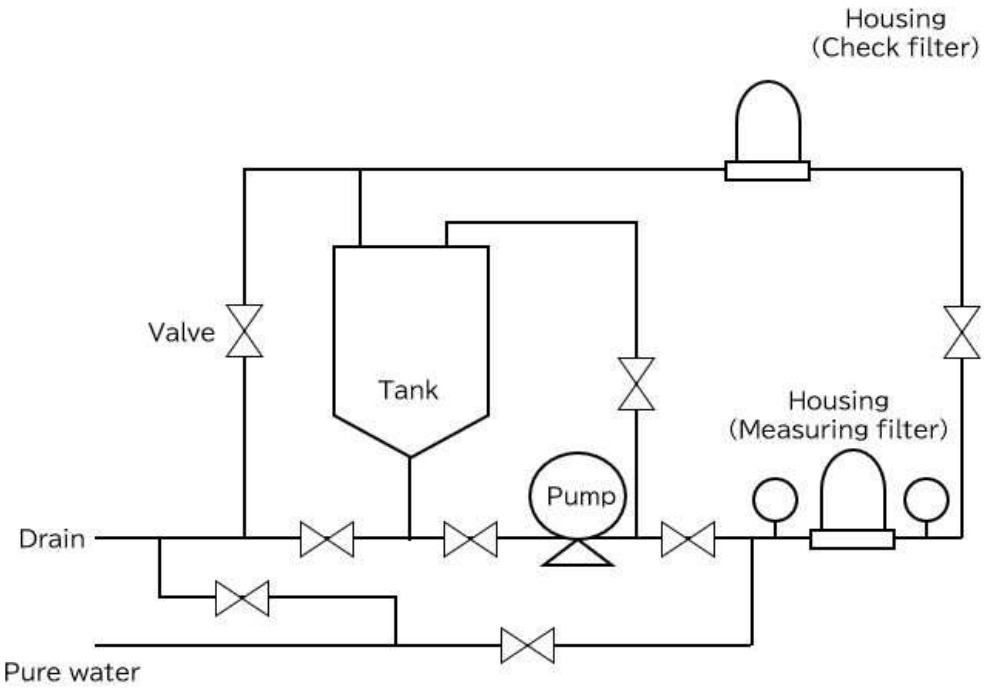
<Procedure>

① Hot water is passed through the filter housing from the upstream side for 30 minutes, followed by cold (room temperature) water for 10 minutes.

② The above hot and cold water flow is one cycle, and the specified cycle is performed.

③ Check the integrity (DF) of filter cartridges after②.

<Schematic Hot Water Resistance Test Line>



【Results】

Catalog. No.	250L-CES-002	Micron Rating	0.20μm
No.	DF(mL/min)		
	Before	After	
1	9	10	
2	10	10	
3	10	9	

※DF standard value: ≦20 mL/min, Measurement solution: Pure Water, Measurement pressure: 0.20MPa【29.0psi/2.0bar】

Catalog. No.	250L-CES-005	Micron Rating	0.45μm
No.	DF(mL/min)		
	Before	After	
1	10	8	
2	8	6	
3	9	9	

※DF standard value: ≦25 mL/min, Measurement solution: Pure Water, Measurement pressure: 0.15MPa【21.8psi/1.5bar】

Catalog. No.	250L-CES-006	Micron Rating	0.65μm
No.	DF(mL/min)		
	Before	After	
1	6	2	
2	5	1	
3	6	2	

※DF standard value: ≦15 mL/min, Measurement solution: Pure Water, Measurement pressure: 0.10MPa【14.5psi/1.0bar】

【Conclusion】

The results of applying repetitive hot and cold water passing to the filter cartridge showed no change in the appearance of the filter before and after the test, and the integrity of the filter cartridge was maintained.

2-5. Potassium Permanganate Consumption Test

【Summary】

This test confirms the amount of potassium permanganate reductant in the filter cartridge.

【Criteria】

The ultrapure water filtered by the filter cartridge after autoclave sterilization (126℃ [258.8℉] x 1 hour) shall be light red after adding reagent. Shall conform to the USP oxidant test using ultrapure water.

【Method】

＜Conditions･Procedure＞

① Sterilize the filter cartridge in the autoclave at 126℃【258.8℉】× 1 hour.
② Set the filter cartridge in the filter housing.
③ Pass ultrapure water through the filter cartridge at 3L/min.
④ Take a sample of 100ml for a total of 10 times, add 10mL of 2N-H_2SO4 and heat for 5 min.
⑤ Add 0.2mL of 0.1N potassium permanganate and boil for 5 min.
⑥ Check that the solution exhibits a slightly red color.

【Results】

No.	Criteria: The color of the solution turns slightly red
1	slightly red
2	slightly red
3	slightly red
4	slightly red
5	slightly red
6	slightly red
7	slightly red
8	slightly red
9	slightly red

【Conclusion】

The filter cartridge after autoclave sterilization (126℃【258. 8℉】x 1 hour) conforms to the USP Oxidizable Substance Test by passing more than 1,000ml of ultrapure water.

3. Specifications

3-1. Materials

Media	:	Polyether sulfone
Support	:	Polypropylene
Core	:	Polypropylene
Cage	:	Polypropylene
End Cap	:	Polypropylene
O-Ring	:	Silicone, EPDM, NBR, FKM, FEP encapsulated FKM
Gasket	:	Silicone, EPDM, NBR, FKM, PTFE

3-2. Dimensions

Total Length	:	125mm, 250mm, 500mm, 750mm
Outer Diameter	:	70.0mm
Inner Diameter	:	25.6(Code 0,5)／26.1(Code F)／29.5(Code 7) mm

3-3. Micron Rating

002	:	0.20μm
005	:	0.45μm
006	:	0.65μm

3-4. Filtration area

0.77m^2／total length 250mm

3-5. Maximum operating differential pressure

＜0.49MPa【71.1psid/4.9bar】at 40℃【104˚F】

3-6. Maximum operating temperature

80℃【176˚F】

3-7. DF(Diffusion)

002 ： ≦20 mL/min, Measurement solution: Pure Water,
Measurement pressure: 0.20MPa【29.0psid/2.0bar】
※Total length 250mm

005 ： ≦25 mL/min, Measurement solution: Pure Water,
Measurement pressure: 0.15MPa【21.8psid/1.5bar】
※Total length 250mm

006 ： ≦15 mL/min, Measurement solution: Pure Water,
Measurement pressure: 0.10MPa【14.5psid/1.0bar】
※Total length 250mm

3-8. Other

Compliance with FDA 21CFR
Compliance with Regulation(EC) No. 1935/2004
Compliance with BSE/TSE

3-9. Reference (Results of other tests)

3-9-1. Water Flow Test
3-9-2. Evaporation Residue Test

3-9-1. Water Flow Test

【Summary】

This test confirms the relationship between flow rate and pressure drop across the filter cartridge.

【Method】

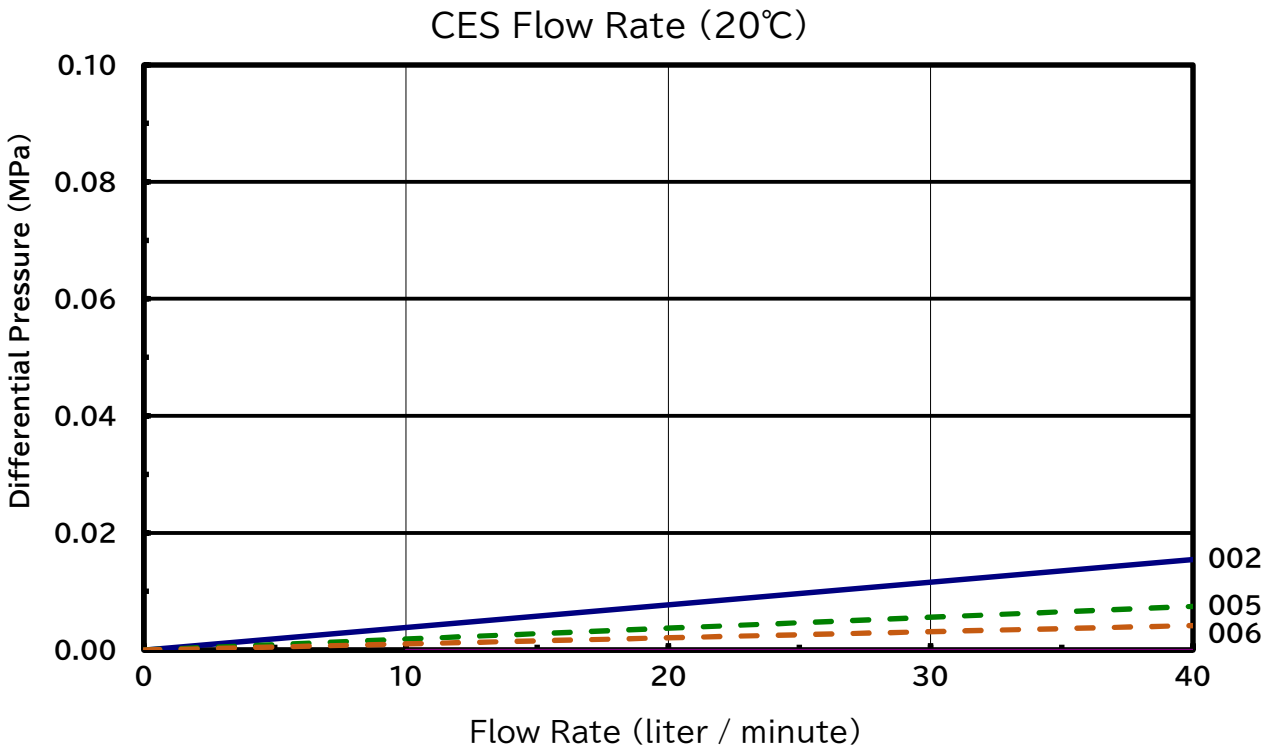
＜Conditions＞

- Fluid : Pure water (20℃)【68°F】
- Filter Size : 250mm

＜Procedure＞

- Set a filter cartridge in the filter housing.
- Adjust the flow to 40mL/min, and measure the pressure drop.
- Adjust the flow to 30mL/min, and measure the pressure drop.
- Adjust the flow to 20mL/min, and measure the pressure drop.
- Adjust the flow to 10mL/min, and measure the pressure drop.

【Results】



3-9-2. Evaporation Residue Test

【Summary】

This test confirms the number of evaporated residue in the filter cartridge.

【Method】

<Content>

Immerse the filter cartridge in the ultrapure water, measure the evaporation to dry.

<Conditions･Procedure>

- Autoclave Sterilization: 126℃【258.8℉】x 1 hour
- Immerse the filter cartridge (250L) in the ultrapure water for 24 hours and evaporate to dry.
- Measure the total evaporated residue.

【Results】

No.	Total evaporation residue(mg)
01	< 5
02	< 5
03	< 5

4. Certificate

4-1. Certification of FDA 21CFR Conformity

Components used in CES filters conform to FDA 21CFR.

【Compliance criteria for materials used】

①Media (Polyether sulfone membranes)	:	§177. 2440
②Support (Polypropylene)	:	§177. 1520
③PP molded products (Polypropylene)	:	§177. 1520
④O-Ring① (Silicone, NBR, FKM)	:	§177. 2600
⑤O-Ring② (FEP encapsulated FKM)	:	§177. 1550
⑥Gasket① (Silicone, NBR, FKM)	:	§177. 2600
⑦Gasket② (PTFE)	:	§177. 1550

4-2. Regulation(EC) No. 1935/2004

The Products meet the requirements for food contact as detailed in European Regulation (EC) No. 1935/2004.

・The Plastic Materials have been assessed in following conditions based on EU No.10/2011

(1) 3% Acetic acid, 100℃, 1hour

(2) 50% Ethanol, 100℃, 1hour

・The products are manufactured at our plant conforming to GMP based on EC No.2023/2006.

＊Applicable Gasket/ O-Ring: Silicone

4-3. Certification of conformity of BSE/TSE

The raw materials (excipients) of polypropylene of CES filter cartridge use fatty acids of animal origin. However, in the manufacturing process of the excipients, BSE inactivation is treated by hydrolysis at a minimum temperature of 200℃【392°F】, 4MPa【40bar】, for 20 minutes.

5. Chemical Resistance Table

<Description of the results>

○ : Usable,
△ : Usable depending on conditions,
× : Non-use significant reduction of strength, etc.

Classification	Chemical Name	Concentration	Results
Acid	Acetic acid	20%	○
	Hydrochloric acid	30%	○
	Sulfuric acid	20%	○
Alkali	Sodium hydroxide	10%	○
	Potassium hydroxide	10%	○
	Ammonia water	28%	○
Alcohol	Methyl alcohol		○
	Ethyl alcohol		○
	n-Propyl alcohol		○
	Isopropyl alcohol (IPA)		○
	n-Butyl alcohol		○
Ether	Dioxane		△
	Tetrahydrofuran (THF)		×
	Ethyl ether		△
Ester	Ethyl acetate		×
Ketone	Acetone		×
	Methyl ethyl ketone (MEK)		×
	Methyl isobutyl ketone (MIBK)		×
Hydrocarbon	n-Hexane		△
	Benzene		△
	Toluene		×
Halogenated hydrocarbon	Chloroform		×
	Freon TMC		×
	Methylene Chloride		×
Amine	Dimethylformamide		×
Aldehyde	Formaldehyde	35%	○
Others	Ferric chloride		○
	Copper sulfate		○
	Mineral oil		△
	Hydrogen peroxide solution	10%	○
	Sodium hypochlorite	10ppm	○

※ The above table represents the result of chemical resistance after 24 hours immersion at room temperature.

※ Chemical resistance depends on the filtration conditions (such as temperature, time, and concentration), please confirm the resistance with actual operating conditions.

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※The content of the validation guide is subject to change without notice.