Data Sheet

AseptiPrime® KS

Hydrophilic Polyethersulfone (PES) Membrane Cartridge Filters

Bio-pharmaceutical manufacturing is a complex, multistep process which involves a very wide variety of process streams under different process conditions at different steps. These process streams include cell culture media, media additives, growth regulators in the upstream and post centrifuge cell harvest supernatants, post viral inactivation intermediates, buffers, and high value product concentrates in the downstream. Filtration and purification of such a wide spectrum of fluid streams, to achieve varied objectives at each step, is quite a challenge for the process owner.

Microfiltration accounts for a very high (approximately 25%) of the filtration and purification costs. Sterilizing filters are a huge component of this cost as these are critical for multiple applications across the entire biopharmaceutical process. Some of these are:

- Sterile filtration of culture media and product concentrates
- Protection of expensive virus filters and chromatography columns
- Control of microbial load throughout the process chain

There is therefore a continuous need to enhance filter throughput with various process streams.

mdi *AseptiPrime® KS* cartridge filters are designed to fulfil the above need. These low protein binding filters, incorporate a very high porosity optimized pre-filter PES membrane with unique pore structure that ensures high loading capacity for suspended contaminants and high volume handling. This results in much higher throughput when compared with other available sterilizing filters.

The robust, highly retentive final membrane layer ensures that **mdi** *AseptiPrime® KS* cartridge filters meet international regulatory requirements for microbial retention and deliver sterile filtrate.

0.2µm *AseptiPrime® KS*

PES Membrane Cartridge Filters for Biopharmaceuticals

Datasheet

mdi 0.2µm *AseptiPrime® KS* cartridge filters are deeply validated for use in Biopharmaceutical applications. These filters are manufactured in class 10,000 clean rooms and ISO 9001 certified facilities.

Packaging is done in polybags for for convenience of taking *AseptiPrime® KS* in clean areas for making disposable assemblies for subsequent sterilization.

Key Features

- Low protein binding
- High throughputs
- Long service life
- Pre-flushed to minimize particulate release after installation
- Non-toxic material of construction
- Absolute retention
- 100% integrity tested
- High flow rates
- Bioburden maintained below 1000 cfu/device
- Endotoxin level certified to be <0.25 EU/ml
- Unique identification number is laser etched on each filter
- Individual certificate of quality for each device
- Sterilizable by Autoclaving/Steaming in place (SIP)

Applications

Sterile filtration

- Cell culture media
- Cell culture media containing serum
- Media additives
- Buffers
- pH adjusters
- Final product concentrates

Validation Services

The regulatory requirements emphasize on the need to validate the efficacy of the filter with drug product under simulated worst-case conditions of use.

mdi provides validation services supported by customized validation protocols and world class test facilities to assist you in filter validations with your specific drug product.

Quality Assurance

mdi quality management system emphasizes on quality by design rather by end product testing. Robust processes are developed for product manufacturing and are continuously monitored to ensure that the products meet their predetermined specifications and lot to lot reproducibility is ensured.

Certificate of Quality

Each cartridge filter is accompanied by individual certificate of quality to ensure traceable documentation at user's end.

It certifies the product compliance to various regulatory as well as user requirements.

Validated for Microbial Retention

Integrity test data have been correlated to actual microbial retention with *Acholeplasma laidlawii* (ATCC 23026) and *B.diminuta* (ATCC 19146) to establish acceptable integrity test values.

Samples from each lot are subjected to microbial challenge test before final lot release.

100% Integrity Tested

Each *AseptiPrime® KS* is tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Flow Rate

Each lot is tested for clean water flow rates to ensure that flow rates are within the specifications.

Adsorption

AseptiPrime® KS filters are validated for low protein binding to ensure minimal active ingredient losses when used for filtration of high value proteins.

Pressure, Temperature Endurance

AseptiPrime® KS filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

Extractables

Extractables/leachables from A*septiPrime® KS* filters, used at various stages of a biopharmaceutical manufacturing process, will add on and may impact the impurity profile of the desired product.

AseptiPrime® KS filters are validated to exhibit low extractables under harsh extraction conditions.

Bioburden Testing

AseptiPrime® KS bioburden is tested as per ISO 11737-1 and assured to be <1000 cfu/device.

Endotoxin Testing

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>.

Total Traceability

AseptiPrime® KS filters come with completely traceable lot numbers and unique identification number to facilitate easy and fast retrieval of manufacturing and quality control data associated with each filter.

These unique lot and identification numbers are laser etched on each filter device and also printed on the labels of the box in which individual filter is packed.

Packaging Integrity

AseptiPrime® KS filters are packed in bags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean roomprocess areas.

Other Regulatory Compliance

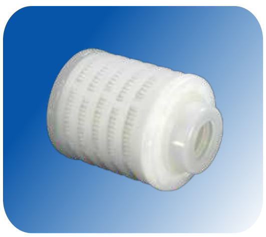
- Complies with USFDA 21 CFR 210.3(b)(6) for fiber release
- Complies with USFDA 21 CFR 177.1520 for fractional dissolution
- Materials of construction tested for toxicity as per Biological Reactivity Tests, In-vivo, USP <88> for class VI Plastics
- Complete filter devices tested for cytotoxicity as per Biological Reactivity Tests, In-vitro, USP <87>

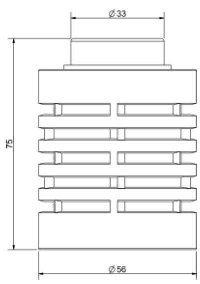
Datasheet

Adapters and Dimensions

2.5" Mini Cartridge Filters

4463 Adapter (E0)





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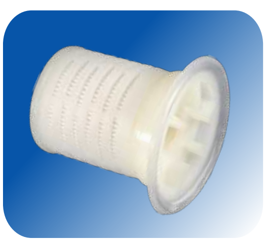
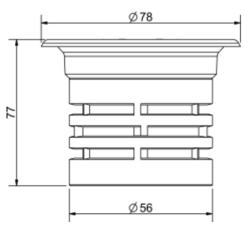
Diameter : 56 mm

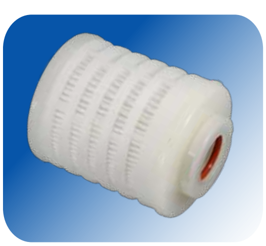
Seal-K Adapter (G0)

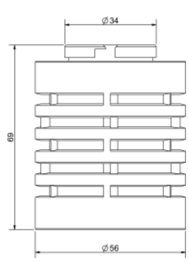




Total Length : 77 mm
Diameter : 56 mm

4463B Adapter (H0)

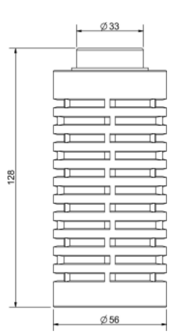




Total Length : 69 mm
Diameter : 56 mm

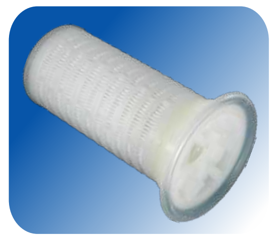
5" Mini Cartridge Filters

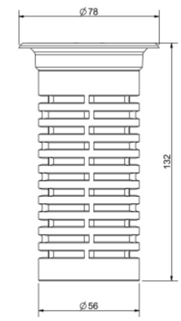
4463 Adapter (E0)



Total Length : 128 mm
Diameter : 56 mm

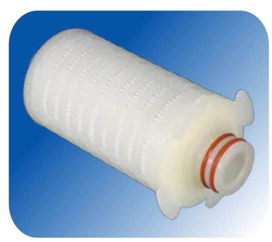
Seal-K Adapter (G0)

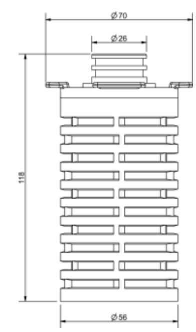




Total Length : 132 mm
Diameter : 56 mm

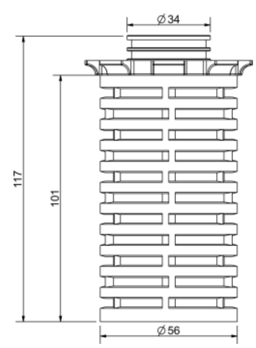
4440 Adapter (U0)





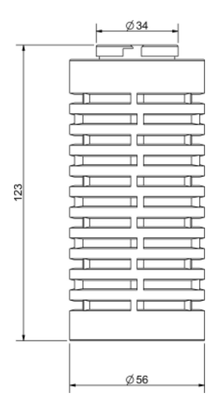
Total Length : 118 mm
Diameter : 56 mm

Seal-O Adapter (F0)



Total Length : 117 mm
Diameter : 56 mm

4463B Adapter (H0)



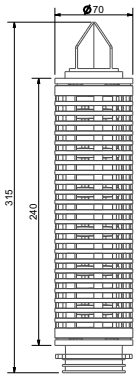
Total Length : 123 mm
Diameter : 56 mm

Adapters and Dimensions

Datasheet

Standard Cartridge Filters

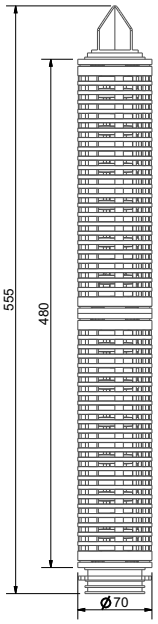
10" Cartridge Filter- 7P Adapter with Fin (A0)



Total Length : 315 mm

Diameter : 70 mm

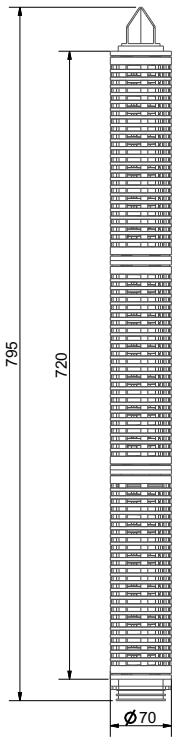
20" Cartridge Filter- 7P Adapter with Fin (A0)



Total Length : 555 mm

Diameter : 70 mm

30" Cartridge Filter- 7P Adapter with Fin (A0)



Total Length : 795 mm

Diameter : 70 mm

Adapter and Elastomers Availability Chart

Mini Cartridge Filters		
Adapters	**2.5”**	**5”**
4463	√	√
4463B	√	√
4440	√	√
Seal-K	√	√
Seal-O	X	√
Seal-M	√	√

Mini Cartridge Filters	
Adapters	**Elastomer**
	Silicone
4463	√
4463B	√
4440	√
Seal-K	X
Seal-O	√
Seal-M	√

Standard Cartridge Filters				
Adapters	**5”**	**10”**	**20”**	**30”**
7P	√	√	√	√
7P without Fin	√	√	√	√
28 with Fin	X	√	√	√
‘O’	X	√	√	√

Standard Cartridge Filters				
Adapters	**Elastomers**			
	Silicone	Viton	EPDM	FEP Encapsulated Viton
7P	√	√	√	√
7P without Fin	√	√	√	√
28 with Fin	√	√	√	X
‘O’	√	√	√	X

Linear Upscaling from Pilot Scale to Production Process

Datasheet

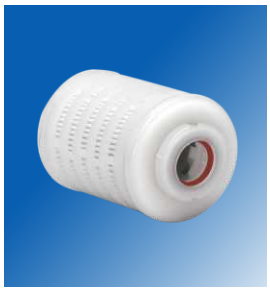
Scientists are concerned about filter fluid interaction impacting the stability, purity, strength etc. of the drug product, and they take a keen interest in filter selection at the formulation development stage itself. Although preliminary compatibility data support initial filter selection, for stability studies detailed filter validations are required to provide enough documented evidence to justify specific filter use.

A critical requirement that needs to be addressed at this stage is of scalability from pilot scale to full scale production processes.

mdi offers a wide range of *AseptiPrime® KS* filters to provide linear scale up from lab scale to production process. While scaling up the process, the appropriate size filter can be selected by increasing the effective filtration area of filter proportionate to the process fluid volumes.

All Materials of construction as well as manufacturing process are identical for all filter devices starting from 1000 cm^2 to 18000cm^2 hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *AseptiPrime® KS* filters there by reducing the additional validation cost and time.

***AseptiPrime® KS*, 2.5"**
EFA: 1000 cm^2



***AseptiPrime® KS*, 5"**
EFA: 2000 cm^2

***AseptiPrime® KS*, 5" Large**
EFA: 3000 cm^2

***AseptiPrime® KS*, 10"**
EFA: 6000 cm^2

***AseptiPrime® KS*, 20"**
EFA: 12000 cm^2

***AseptiPrime® KS*, 30"**
EFA: 18000 cm^2

***EFA: Effective Filtration Area**

Specifications

Mini Cartridge Filters

Datasheet

Construction		
Membrane	Hydrophilic PES	
Support Layers	Polyester	
Plastic Parts	Polypropylene	
O rings	Silicone	
Final Filter Pore Size	0.1µm	0.2µm
Pre-Filter Pore Size	0.3µm and 0.5µm	0.5µm
Integrity Testing / Retention		
Bubble Point	≥ 31psi (2.18 Kg/cm^2) with 50% IPA/Water Solution	≥ 50psi (3.52Kg/cm^2) with Water
Microbial Retention	LRV >7 for *Acholeplasma laidlawii* (ATCC 23026) per cm^2	LRV >7 for *Brevundimonas diminuta* (ATCC 19146) per cm^2
Size		
Size	2.5″	5″
Effective Filtration Area (Nominal)	1000cm^2	2000cm^2
Operational		
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm^2)	
Max. Differential Pressure	50 psi (3.5 Kg/cm^2) @ 25 °C	
Reverse Pressure	< 0.7 Kg/cm^2 (10 psi) @ 25 °C	
Sterilization	In-line steam sterilizable at 135°C for 30 minutes at 3 psi (0.21 kg/cm^2), 25 cycles	
Assurance		
Toxicity	Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics	
Cytotoxicity	Passes Biological Reactivity tests, In Vitro, USP <87> for cytotoxicity	
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>	
Bioburden	Bioburden level is < 1000 cfu/filter device as per ISO 11737-1	
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections	
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release	
TOC and Conductivity	Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after a 3 liter WFI flush	
pH Compatibility	Compatible with pH range of 1 - 10	
Extractables with WFI	Passes NVR test as per USP <661>	
Indirect Food Additives	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520	
Oxidizable Substances	Passes test as per USP <1231>	
Quality Management System	ISO-9001 Certified	
USFDA	DMF No. 015554	

Specifications

Standard Cartridge Filters

Datasheet

Construction				
Membrane	Hydrophilic PES			
Support Layers	Polyester			
Plastic Parts	Polypropylene			
O rings	Silicone			
	Viton			
	EPDM			
	FEP Encapsulated Viton			
Final Filter Pore Size	0.1µm		0.2µm	
Pre-Filter Pore Size	0.3µm and 0.5µm		0.5µm	
Integrity Testing / Retention				
Bubble Point	≥ 31psi (2.18 Kg/cm^2) with 50% IPA/Water Solution		≥ 50psi (3.52Kg/cm^2) with Water	
Air Diffusion Flow (10" Filter)	≤ 29 ml/min @ 50 psi (3.52 Kg/cm^2) with Water		≤ 30 ml/min @ 37 psi (2.6 Kg/cm^2) with Water	
Microbial Retention	LRV >7 for *Acholeplasma laidlawii* (ATCC 23026) per cm^2		LRV >7 for *Brevundimonas diminuta* (ATCC 19146) per cm^2	
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000cm^2	6000cm^2	12000cm^2	18000cm^2
Operational				
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm^2)			
Max. Differential Pressure	50 psi (3.5 Kg/cm^2) @ 25 °C			
Reverse Pressure	< 0.7 Kg/cm^2 (10 psi) @ 25 °C			
Sterilization	In-line steam sterilizable at 135°C for 30 minutes at 3 psi (0.21 kg/cm^2), 25 cycles			
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pH Compatibility	Compatible with pH range of 1 - 10			
Extractables with WFI	Passes NVR test as per USP <661>			
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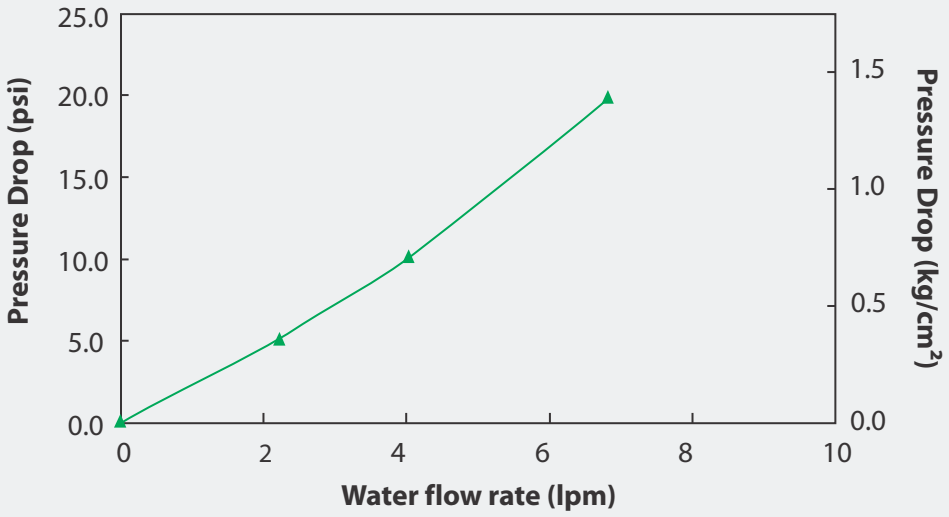
Oxidizable Substances	Passes test as per USP <1231>			
Quality Management System	ISO-9001 Certified			
USFDA	DMF No. 015554			

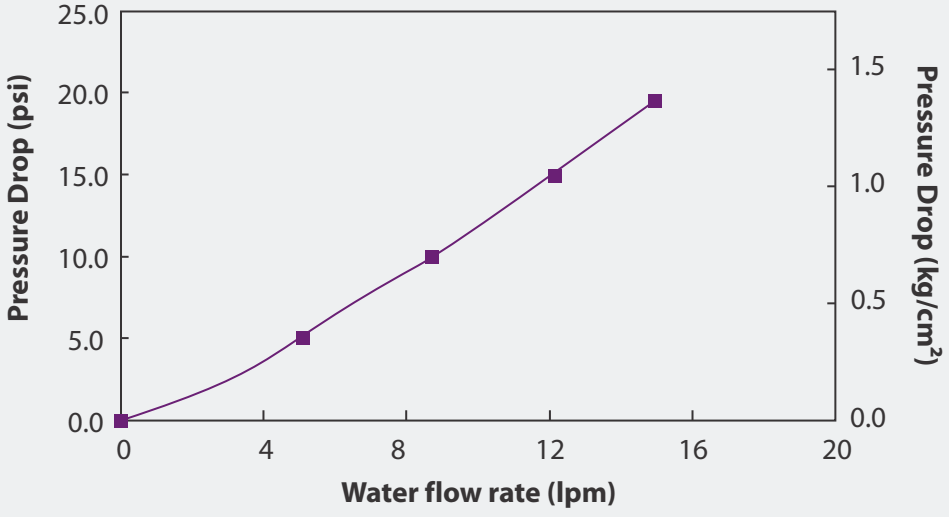
Typical Water Flow Rates
Mini Cartridge Filters

Datasheet

0.1µm *AseptiPrime*® KS, 2.5" Mini Cartridge Filters



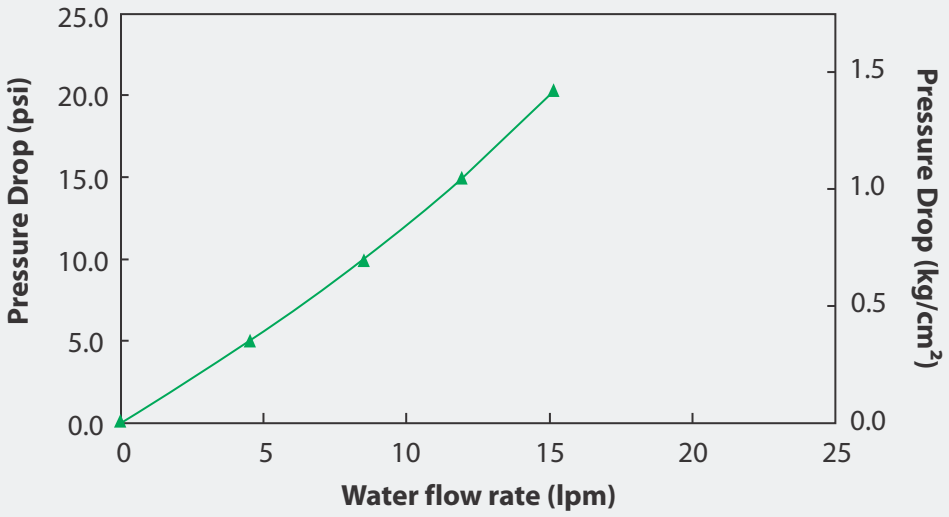
0.1µm *AseptiPrime*® KS, 5" Mini Cartridge Filters



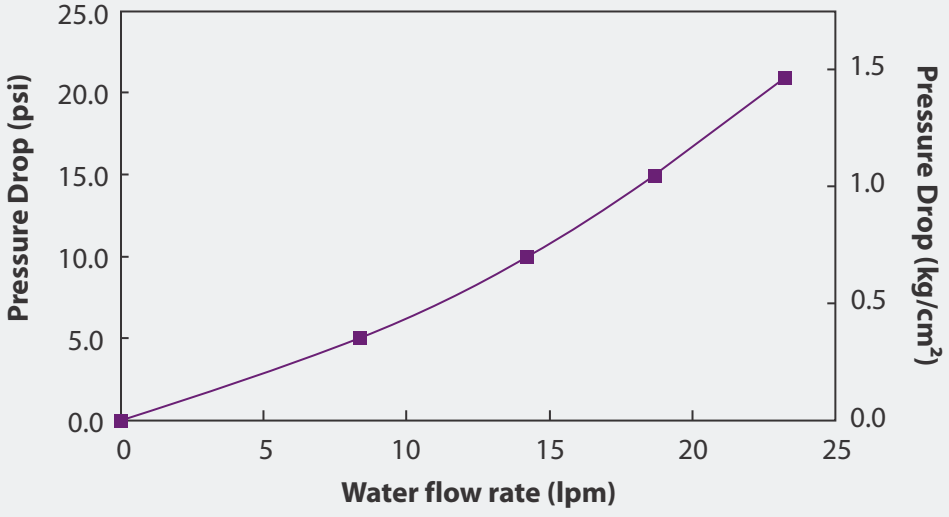
Typical Water Flow Rates
Mini Cartridge Filters

Datasheet

0.2µm *AseptiPrime® KS*, 2.5" Mini Cartridge Filters



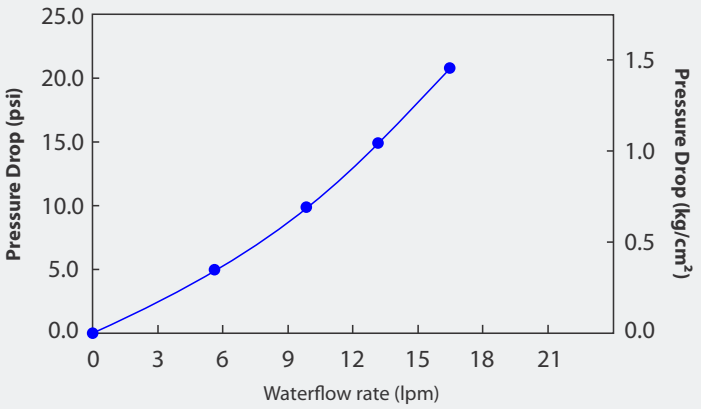
0.2µm *AseptiPrime® KS*, 5" Mini Cartridge Filters



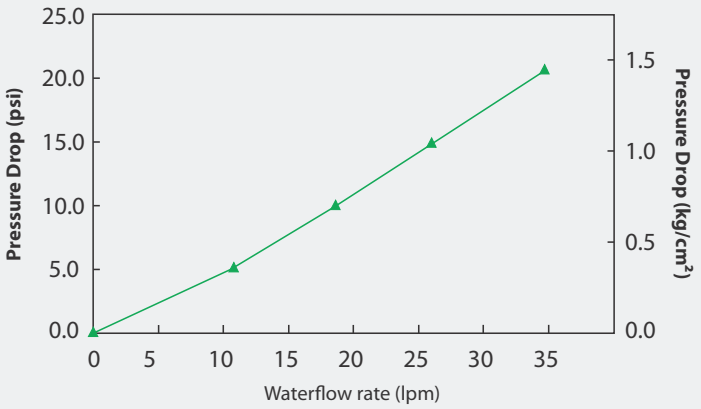
Typical Water Flow Rates
Standard Cartridge Filters

Datasheet

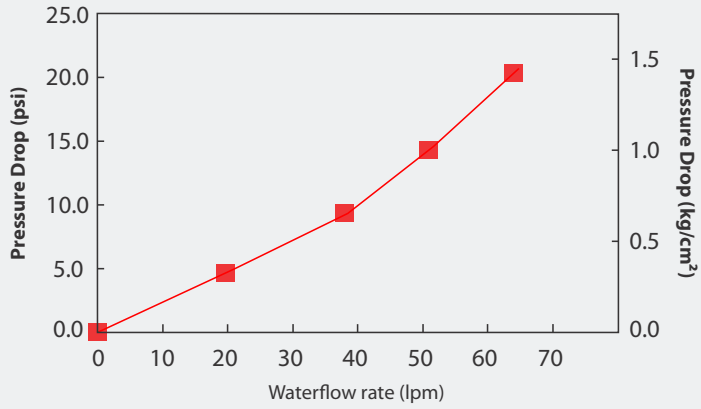
0.1µm *AseptiPrime*® KS, 5" Standard Cartridge Filters



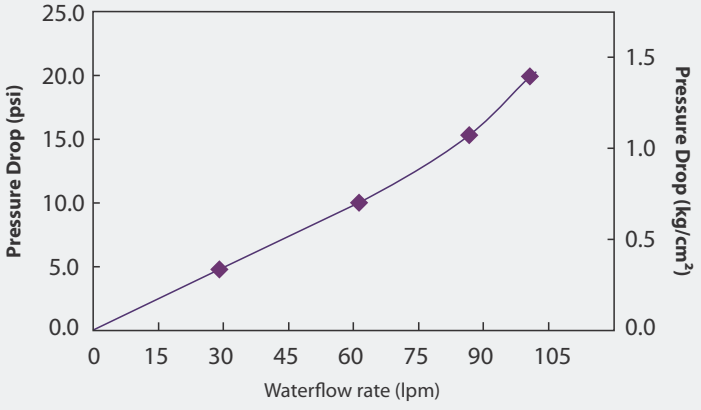
0.1µm *AseptiPrime*® KS, 10" Standard Cartridge Filters



0.1µm *AseptiPrime*® KS, 20" Standard Cartridge Filters



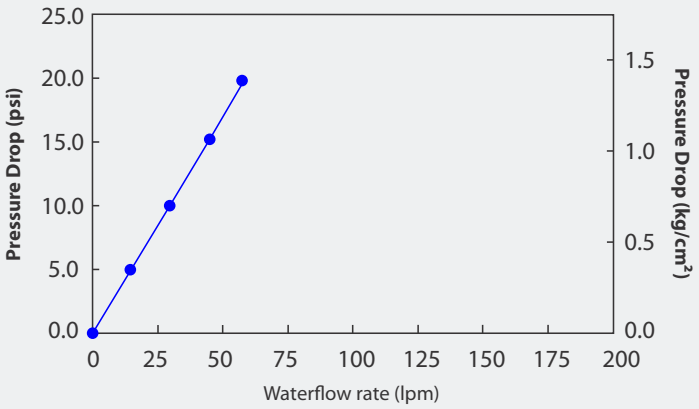
0.1µm *AseptiPrime*® KS, 30" Standard Cartridge Filters



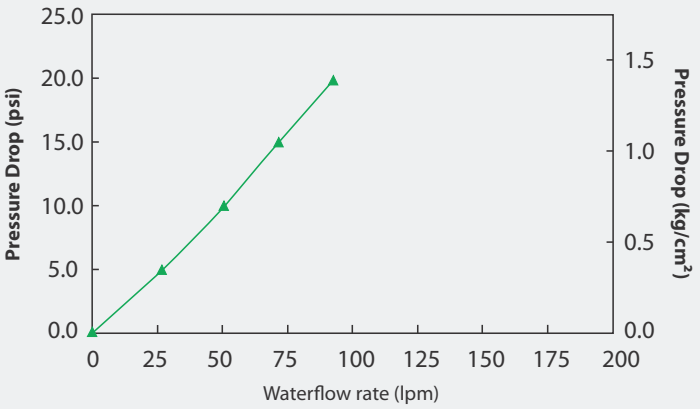
Typical Water Flow Rates
Standard Cartridge Filters

Datasheet

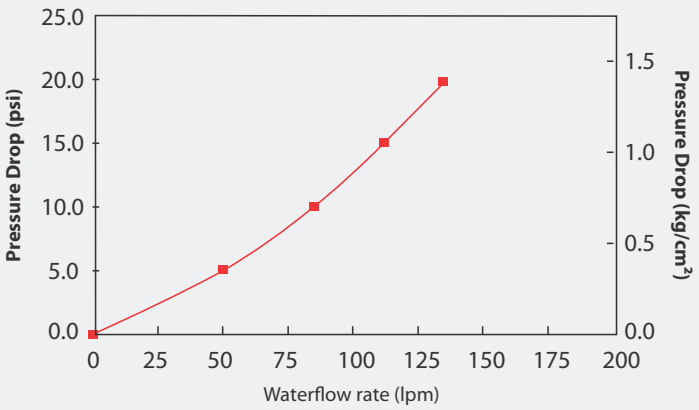
0.2µm *AseptiPrime® KS*, 5" Standard Cartridge Filters



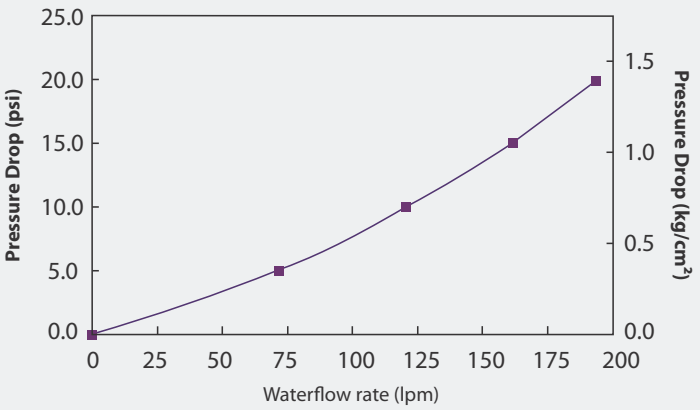
0.2µm *AseptiPrime® KS*, 10" Standard Cartridge Filters



0.2µm *AseptiPrime® KS*, 20" Standard Cartridge Filters



0.2µm *AseptiPrime® KS*, 30" Standard Cartridge Filters



Ordering Information

AseptiPrime® KS PES Membrane Mini Cartridge Filter

Type	
	Code
AseptiPrime® KS (0.3µm Upstream)	CKH9
AseptiPrime® KS (0.5µm Upstream)	CKH7

Size	
	Code
2.5″	50
5″	53

Pore Size	
	Code
0.1µm	36
0.2µm*	01

Adapter	
	Code
4463	E0
4463B	H0
4440	U0
Seal-K	G0**
Seal-O	F0***
Seal-M	J0

Elastomer	
	Code
Silicone	SS

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CKH7	50	01	E0	SS	1	01

*0.2µm pore size filters are available with 0.5µm upstream layer only

**G0 adapter code is not available with any elastomer. Please mention XX in place of elastomer code while ordering

***Adapter code F0 is available only in 5″ cartridge filters.

AseptiPrime® KS PES Membrane Standard Cartridge Filter

Type	
	Code
AseptiPrime® KS (0.3µm Upstream)	CKH9
AseptiPrime® KS (0.5µm Upstream)	CKH7

Size	
	Code
5″*	53
10″	54
20″	55
30″	56

Pore Size	
	Code
0.1µm	36
0.2µm**	01

Adapter	
	Code
7P	A0
7P without fin	A1
28 with fin	C0
'O'	D0

Elastomer	
	Code
Silicone	SS
EPDM	SE
Viton	SV
FEP Encapsulated Viton	FV***

Sterility	
	Code
Non Sterile	1

Pack Size	
	Code
1	01

Example:

CKH7	54	01	A1	SS	1	01

*Size 5" is available in Adapter Code A0 (7P) and A1 (7P without fin) only

**0.2µm pore size filters are available with 0.5µm upstream layer only

**FV is available in adapter code A0 (7P) and A1 (7P without fin) only

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