

Data Sheet

ClariSure® GK

Hydrophilic Polyethersulfone (PES) Membrane Cartridge Filters

Intermediate process fluids in Biopharmaceutical manufacturing are difficult to filter as these have a varying contamination profile. Processes owners are continuously looking for efficient microfiltration solutions:

- Offering absolute retentions for colloidal particles, lipids, cell organelles and microprecipitates
- High throughputs to achieve process economy

mdi polyethersulfone (PES) membrane cartridge filters *ClariSure® GK* are disposable filtration devices for clarification of heavily particle laden solutions or colloidal suspensions. These are especially suited for serum and plasma applications. These cartridges contain an upstream microglassfiber layer and a polyethersulfone membrane layer on the downstream.



The upstream microglassfiber layer retains large size particulate contamination and colloidal particles to protect premature clogging of downstream side PES membrane layer. Thus it gives higher throughputs resulting in better economics.

mdi *ClariSure® GK* filters are validated for key performance parameters such as chemical compatibility, extractables, heat stability and flow rates. These are available in a variety of sizes to suit specific microfiltration needs in critical and specialized process applications.

mdi ClariSure® GK 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.

Key Features

- Low protein binding
- High throughputs
- Long service life
- Pre-flushed to minimize particulate release after installation
- Non-toxic material of construction
- 100% integrity tested
- High flow rates
- Unique identification number is laser etched on each filter
- Individual certificate of quality for each device
- Sterilizable by Autoclaving/Steaming in place (SIP)

Applications

- Precipitate removal post viral inactivation
- Pre-filtration of cell culture media
- Pre-filtration of serum and other viscous biological
- Pre-filtration of serum solutions
- Clarification of cell harvest supernatant
- Pre-filtration of high value difficult to filter drug solutions
- Polishing of turbid solutions

Quality Assurance

mdi quality management system emphasizes on quality by design rather than 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.

100% Integrity Tested

Each *ClariSure*[®] GK 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

ClariSure[®] GK filters are validated for low protein binding to ensure minimal active ingredient losses when used for filtration of high value proteins.

Pressure, Temperature Endurance

ClariSure[®] GK filters are validated to endure high operating pressure and temperature conditions which may be encountered during use.

Extractables

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

ClariSure[®] GK filters are validated to exhibit low extractables under harsh extraction conditions.

Total Traceability

ClariSure[®] GK 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

ClariSure[®] GK filters are packed in bags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room process 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

Adapters and Dimensions

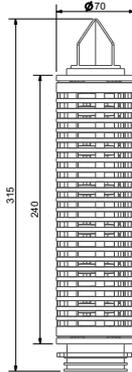
2.5" Mini Cartridge Filters



Adapters and Dimensions

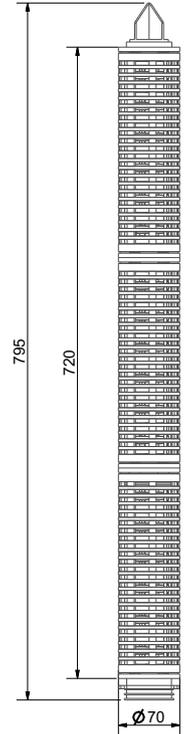
Standard Cartridge Filters

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



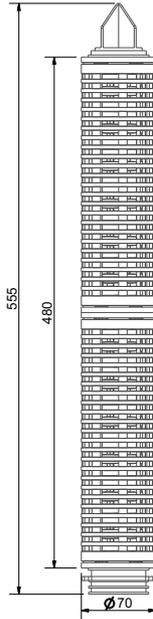
Total Length : 315 mm
Diameter : 70 mm

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



Total Length : 795 mm
Diameter : 70 mm

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



Total Length : 555 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

mdi offers a wide range of *ClariSure*® GK 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 cm² to 15000cm² hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *ClariSure*® GK filters there by reducing the additional validation cost and time.



ClariSure® GK, 2.5"
EFA: 1000 cm²



ClariSure® GK, 5"
EFA: 1500 cm²



ClariSure® GK, 5" Large
EFA: 2500 cm²



ClariSure® GK, 10"
EFA: 5000 cm²



ClariSure® GK, 20"
EFA: 10000 cm²



ClariSure® GK, 30"
EFA: 15000 cm²

*EFA: Effective Filtration Area

Specifications

Mini Cartridge Filters

Datasheet

Construction

Membrane	Hydrophilic PES
Pre-filter	Microglassfiber
Support Layers	Polyester
Plastic Parts	Polypropylene
O rings	Silicone

Size

Size	2.5"	5"
Effective Filtration Area (Nominal)	1000cm ²	1500cm 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	Autoclavable/Steam Sterilized at 121°C for 30 minute, 25 Cycles.

Assurance

Toxicity	Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics
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
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

Construction

Membrane	Hydrophilic PES
Pre-filter	Microglassfiber
Support Layers	Polyester
Plastic Parts	Polypropylene
O rings	Silicone
	Viton
	EPDM
	FEP Encapsulated Viton

Size

Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	2500cm ²	5000cm ²	10000cm ²	15000cm 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	Autoclavable/Steam Sterilized at 121°C for 30 minute, 25 Cycles.

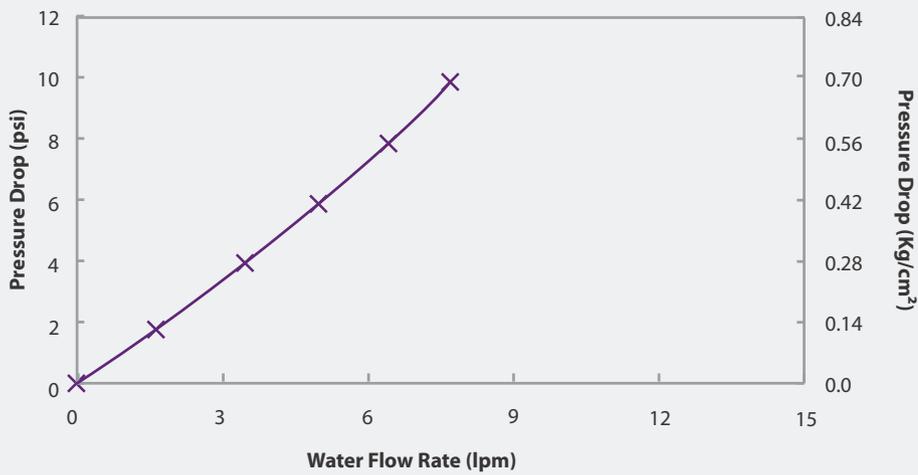
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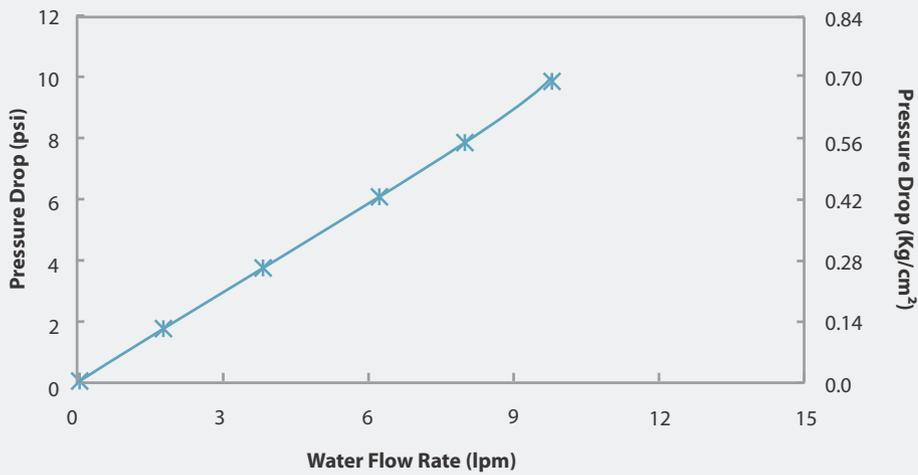
Typical Water Flow Rates

Mini Cartridge Filters

0.5 μ m ClariSure[®] GK, 2.5" Mini Cartridge Filters



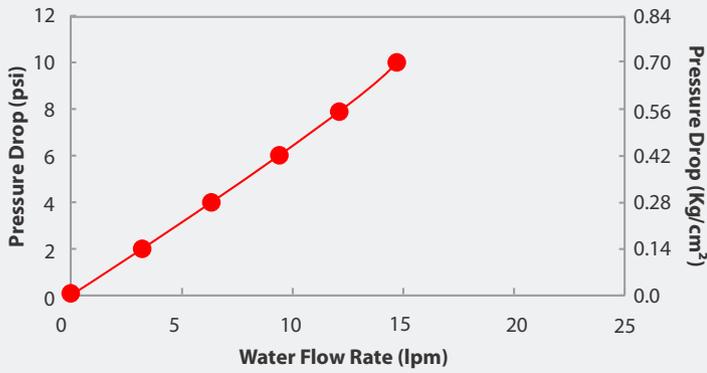
0.5 μ m ClariSure[®] GK, 5" Mini Cartridge Filters



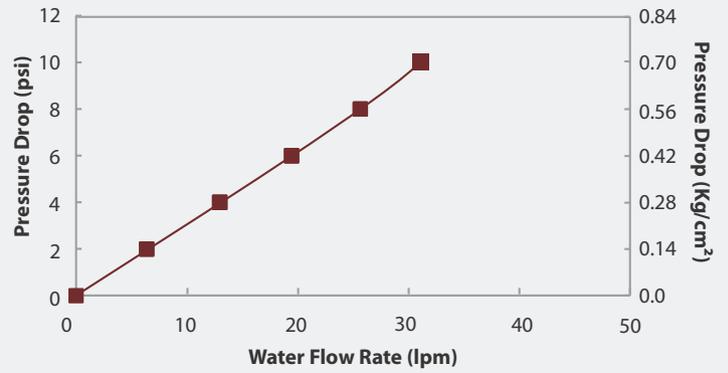
Typical Water Flow Rates Standard Cartridge Filters

Datasheet

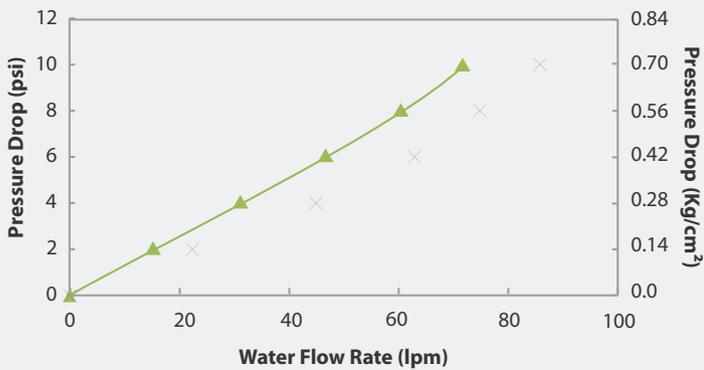
0.5µm ClariSure® GK, 5" Standard Cartridge Filters



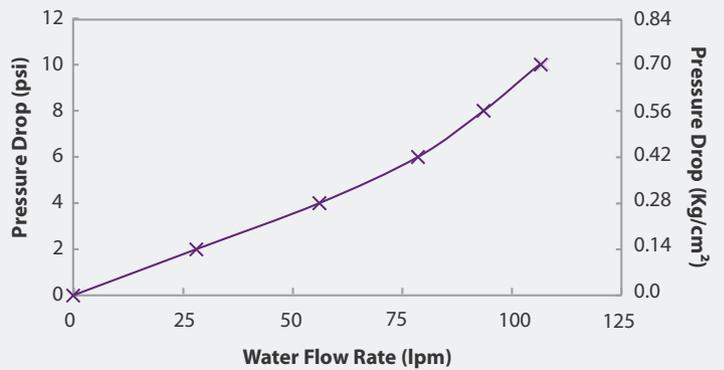
0.5µm ClariSure® GK, 10" Standard Cartridge Filters



0.5µm ClariSure® GK, 20" Standard Cartridge Filters



0.5µm ClariSure® GK, 30" Standard Cartridge Filters



ClariSure® GK PES Membrane Mini Cartridge Filter

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure® GK	CGKX	2.5"	50	0.1µm	36	4463	E0	Silicone	SS	Non Sterile	1	1	01
		5"	53	0.2µm	01	4463B	H0						
				0.5µm	04	4440	U0						
						Seal-K	G0*						
						Seal-O	F0**						
						Seal-M	J0						

Example:

CGKX	50	01	E0	SS	1	01
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*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.

ClariSure® GK PES Membrane Standard Cartridge Filter

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure® GK	CGKX	5"*	53	0.1µm	36	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	0.2µm	01	7P without fin	A1	EPDM	SE				
		20"	55	0.5µm	04	28 with fin	C0	Viton	SV				
		30"	56			'O'	D0	FEP Encapsulated Viton	FV***				

Example:

CGKX	54	01	A1	SS	1	01
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*Size 5" is available in Adapter Code A0 (7P) and A1 (7P without fin) only

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

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