



Data Sheet

ClariSure® PL

Polypropylene Media Cartridge Filters

mdi ClariSure® PL cartridge filters are very high flow rate, high retention efficiency, large area filtration devices of 100% polypropylene construction.

These filters are ideal for applications requiring filtration of very large volumes of fluid without compromising on the filtrate quality.

Applications

- Filtration of organic solvents in non sterile API
- Bottle washing in oral formulations
- Clarification of Buffers
- Process water
- Dyes and chemicals

Key Features

- Very high retention efficiency (99.99%)
- Non media migrating
- Very high flow rates
- Wide chemical compatibility
- Biologically inert
- High throughputs
- Non-toxic material of construction

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 lot 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.

Flow Rate

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

Pressure, Temperature Endurance

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

Extractables

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

ClariSure® PL filters are validated to exhibit low extractables under harsh extraction conditions.

Total Traceability

ClariSure® PL filters come with completely traceable lot numbers to facilitate easy and fast retrieval of manufacturing and quality control data associated with each filter.

These unique lot 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® PL 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.

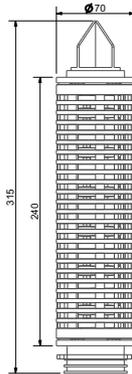
Other Regulatory Compliance

- 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

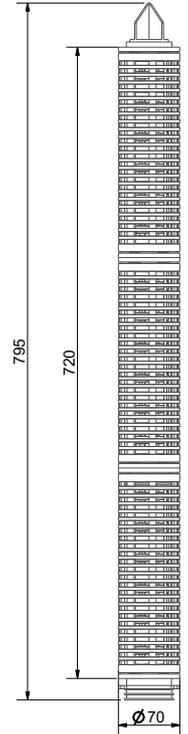
Standard Cartridge Filters

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



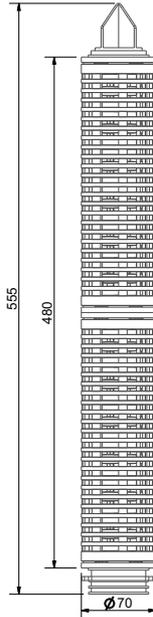
Total Length : 315 mm
Diameter : 70 mm

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

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*® PL 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 2500 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*® PL filters there by reducing the additional validation cost and time



ClariSure® PL, 5" Large
EFA: 2500 cm²



ClariSure® PL, 10"
EFA: 5000 cm²



ClariSure® PL, 20"
EFA: 10000 cm²



ClariSure® PL, 30"
EFA: 15000 cm²

*EFA: Effective Filtration Area

Specifications

Standard Cartridge Filters

Construction

Filter Media	Polypropylene		
Support Layers	Polypropylene		
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		

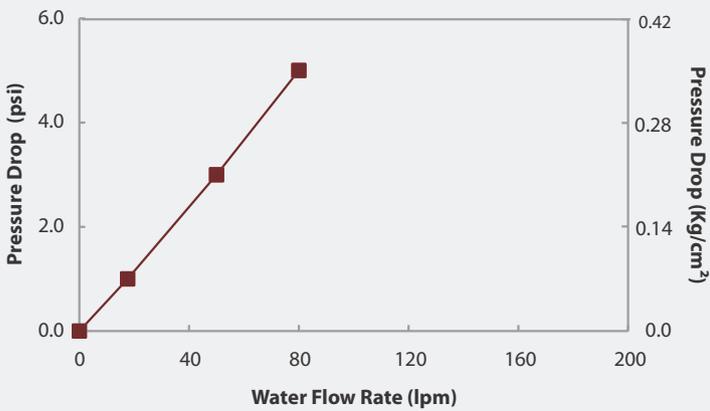
Assurance

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

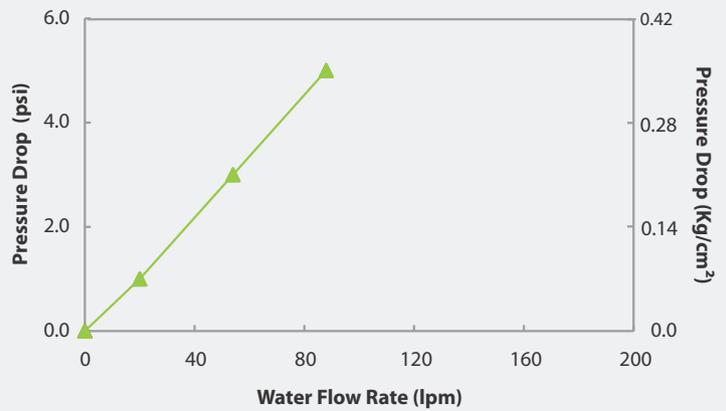
Typical Water Flow Rates Standard Cartridge Filters

Datasheet

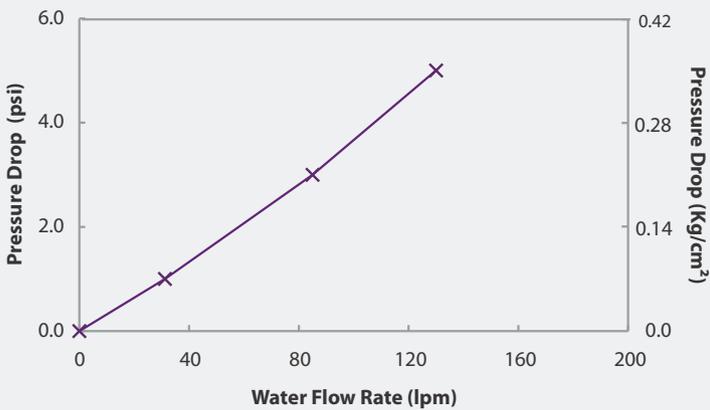
1 μm ClariSure[®] PL, 10" Standard Cartridge Filters



2.5 μm ClariSure[®] PL, 10" Standard Cartridge Filters



5 μm ClariSure[®] PL, 10" Standard Cartridge Filters



ClariSure® PL Standard Cartridge Filter

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure® PL	CPPL	5"*	53	1 µm	05	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	2.5 µm	06	7P without fin	A1	EPDM	SE				
		20"	55	3 µm	16	28 with fin	C0	Viton	SV				
		30"	56	5 µm	07	'O'	D0	FEP Encapsulated Viton	FV**				
				10 µm	08								
				20 µm	11								

Example:

CPPL	54	05	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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