Clarisure® PP

Polypropylene Media Cartridge Filters

DATASHEET

MDI *ClariSure*® PP polypropylene media cartridge filters are 100% polypropylene construction precision filtration devices. These are very high retention efficiency pleated cartridge filters offering large filtration area.

These filters are used as terminal filters in applications requiring highly efficient particulate removal.

Applications

- Polishing filtration of Non Sterile API
- Filtration of precipitating agents
- Filtration of wash solvents for final non sterile API
- Filtration of air to dryers and micronizers
- DM water tank venting
- Final wash water for Ampoule/Vial washing and Bung washing

Key Features

- Very high retention efficiency (99.99%)
- No media migrating
- Very high flow rates
- Wide chemical compatibility
- Biologically inert
- High throughputs
- Non-toxic material of construction

DST CPPPXXX2404A

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

Extractables

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

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

Total Traceability

ClariSure® PP 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® PP 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.

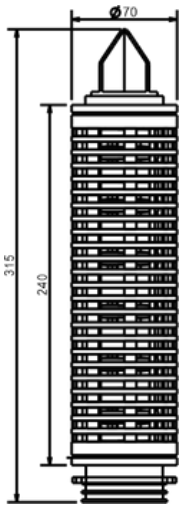
Other Regulatory Compliance

- 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

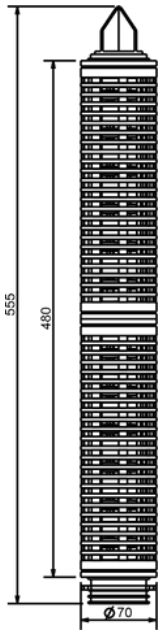
Standard Cartridge Filters

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



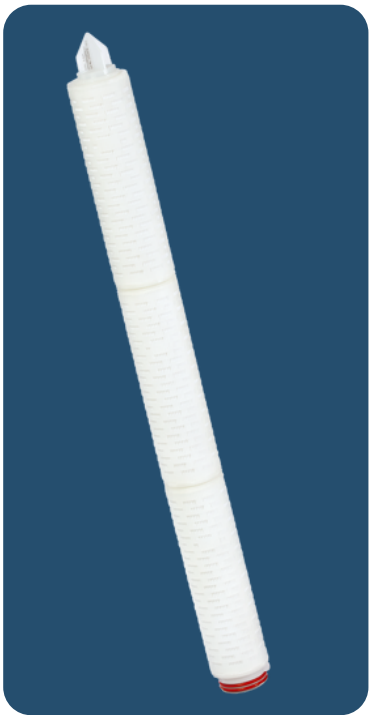
Total Length : 315 mm
Diameter : 70 mm

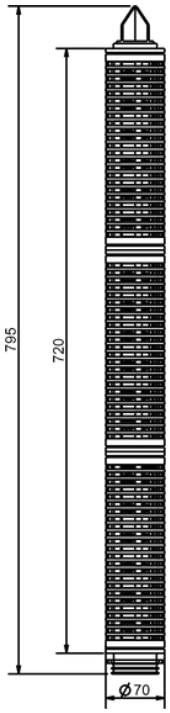
20” Cartridge Filter- 7P Adapter with Fin (A0)



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

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

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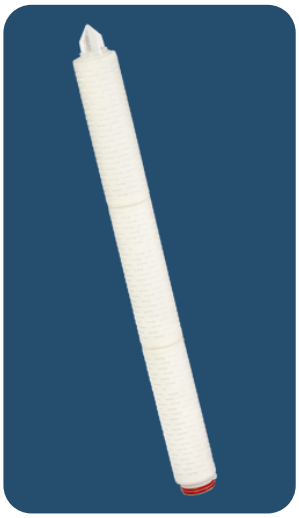
MDI offers a wide range of *ClariSure*® PP filters to provide linear scale up from lab scale to production process. While scaling up the process, the appropriate size filter can be selected by increasing the effective filtration area of filter proportionate to the process fluid volumes.

All Materials of construction as well as manufacturing process are identical for all filter devices starting from 2500 cm^2 to 15000 cm^2 hence process scaling can be facilitated without triggering additional validation studies for given process conditions. MDI provides complete documentation for each of the *ClariSure*® PP filters thereby reducing the additional validation cost and time

***Clarisure*® PP, 5" Standard**
EFA: 2500 cm^2

***Clarisure*® PP, 10"**
EFA: 5000 cm^2

***Clarisure*® PP, 20"**
EFA: 10000 cm^2



***Clarisure*® PP, 30"**
EFA: 15000 cm^2

*EFA: Effective Filtration Area

Specifications

Standard Cartridge Filters

DATASHEET

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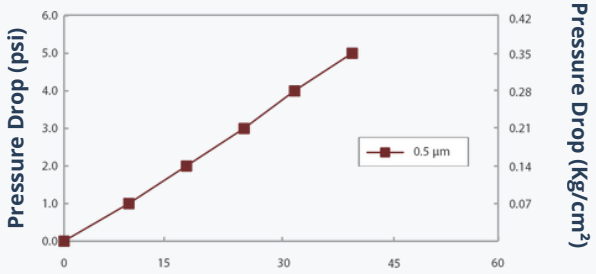
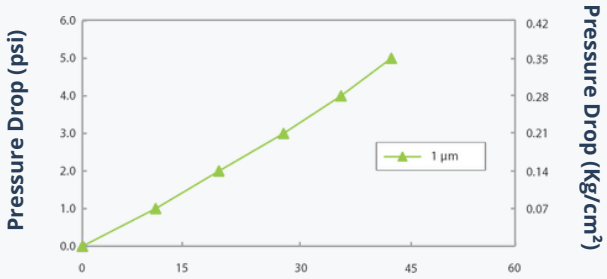
Construction					
Filter Media	Polypropylene				
Support Layers	Polypropylene				
Plastic Parts	Polypropylene				
O rings	Silicone				
	Viton				
	EPDM				
	FEP Encapsulated Viton				
Size					
Size	5"	10"	20"	30"	
Effective Filtration Area (Nominal)	2500cm²	5000cm²	10000cm²	15000cm²	
Operational					
Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm²)				
Max. Differential Pressure	50 psi (3.5 Kg/cm²) @ 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

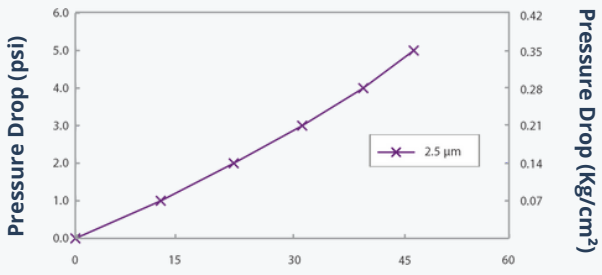
0.5µm *ClariSure*® PP, 10" Standard Cartridge Filters



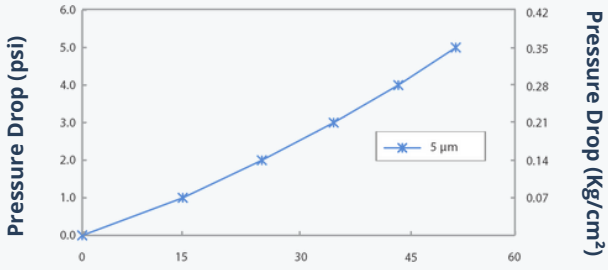
1 µm *ClariSure*® PP, 10" Standard Cartridge Filters



2.5µm *ClariSure*® PP, 10" Standard Cartridge Filters

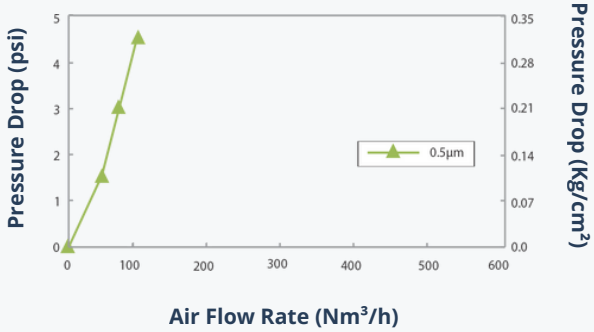


5µm *ClariSure*® PP, 10" Standard Cartridge Filters

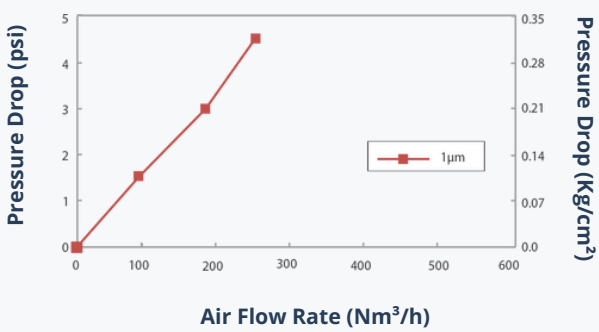


Air Flow Rates
Standard Cartridge Filters

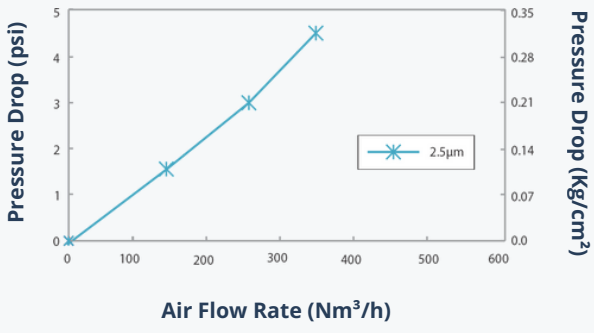
0.5µm *ClariSure*® PP, 10" Standard Cartridge Filters



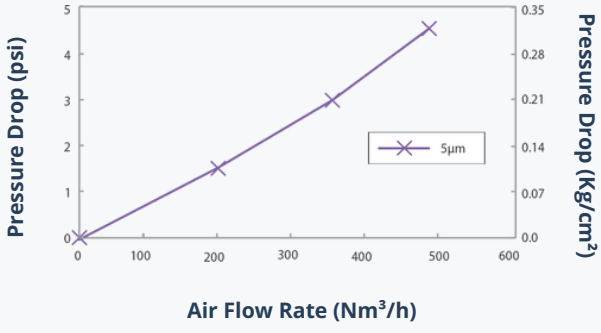
1 µm *ClariSure*® *PP*, 10" Standard Cartridge Filters



2.5µm *ClariSure*® PP, 10" Standard Cartridge Filters



5µm *ClariSure*® PP, 10" Standard Cartridge Filters



Ordering Information

Clarisure® PP Standard Cartridge Filter

Type	
	Code
Clarisure® PP	CPPP

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

Pore Size	
	Code
0.2µm	01
0.5 µm	04
1 µm	05
1.2 µm	10
2 µm	15
2.5 µm	06
3 µm	16
5 µm	07
8 µm	17
10 µm	08
20 µm	11
30 µm	19

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:

CPPP	54	04	A1	SS	1	01

*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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