



Data Sheet

ClariSure® DP

Polypropylene Media Cartridge Filters

mdi ClariSure® DP polypropylene cartridge filters have been designed for medium efficiency particle removal applications from liquids and air/gases. Primarily used for pre-filtration purposes, these cartridge filters can also be used for terminal filtration in non-critical applications. The all polypropylene construction imparts the filter with very wide chemical compatibility.

mdi ClariSure® DP cartridge filters are available in different pore sizes to suit a multitude of applications.

Applications

- Filtration of feed water to RO plants
- Filtration of re-circulation water in Ampoule/ Vial washing
- Clarification of Buffers

Key Features

- Retention efficiency (99.9%)
- High dirt holding capacity
- High flow rates
- Non media migrating
- Wide chemical compatibility
- Biologically inert
- Non-toxic material of construction

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

Extractables

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

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

Total Traceability

ClariSure[®] DP 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[®] DP 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.

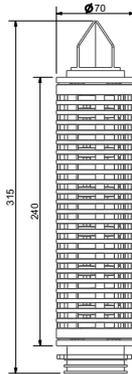
Other Regulatory Compliance

- 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

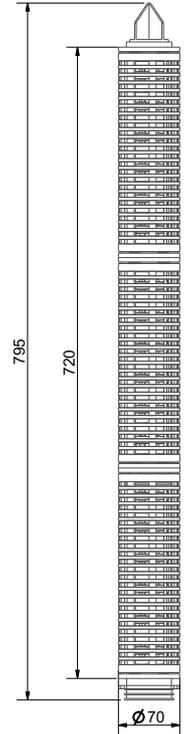
Standard Cartridge Filters

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



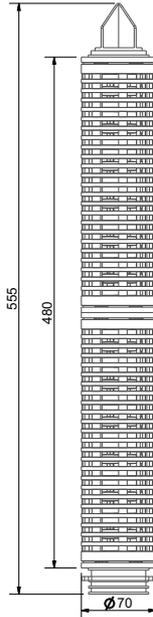
Total Length : 315 mm
Diameter : 70 mm

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*® DP 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 2000 cm² to 12000 cm² hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *ClariSure*® DP filters there by reducing the additional validation cost and time



ClariSure® PP, 5" Large
EFA: 2000 cm²



ClariSure® PP, 10"
EFA: 4000 cm²



ClariSure® PP, 20"
EFA: 8000 cm²



ClariSure® PP, 30"
EFA: 12000 cm²

*EFA: Effective Filtration Area

Specifications

Standard Cartridge Filters

Datasheet

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)	2000cm ²	4000cm ²	8000cm ²	12000cm 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			

Ordering Information

Datasheet

ClariSure® DP Standard Cartridge Filter

Type		Size		Pore Size		Adapter		Elastomer		Sterility		Pack Size	
	Code		Code		Code		Code		Code		Code		Code
ClariSure® DP	CPDP	5"*	53	1 µm	05	7P	A0	Silicone	SS	Non Sterile	1	1	01
		10"	54	1.5 µm	14	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								
				30 µm	19								
				40 µm	20								

Example:

CPDP	54	07	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

Advanced Microdevices Pvt. Ltd.

20-21, Industrial Area, Ambala Cantt-133 006, INDIA

Tel : +91-171-2699290, 2699471

E-mail : info@mdimembrane.com

Website : www.mdimembrane.com