



ClariCap® PP Polypropylene Media Capsule Filters Data Sheet

mdi polypropylene capsule filters type *ClariCap® PP* have been designed for particle removal applications in liquids and air/gases. These are suitable for use in pharmaceutical and biopharmaceutical prefiltration applications.

The pleated polypropylene filtration media and all polypropylene polymer housing has high heat resistance and exhibits very wide chemical compatibility. These offer high retention efficiency thereby enhancing the performance (life and efficiency) of terminal sterilization filters.

mdi *ClariCap® PP* capsule filters offer ease of use because of negligible standard stainless steel filtration housing assemblies. These also do away with the requirement of cleaning and validation of conventional filtration housing assemblies.

Applications

- Prefiltration of high value drug solutions
- Prefiltration of drug vehicles
- Prefiltration of air to small fermentors

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 capsule 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

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

These filters are also validated for high burst pressure to ensure user safety in case of inadvertent pressure build-up.

Extractables

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

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

Total Traceability

ClariCap® PP 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.

Endotoxin Testing

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

Packaging Integrity

ClariCap® PP filters are fitted with vent caps and are packed in bags to ensure package integrity during transit as well as to prevent particulate contamination while transferring to clean room assembly or 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

Widest Range of End Connections

mdi ClariCap® PP filters offer a wide range of reliable end connections for functional convenience and customized connectivity.

Validated for Performance

These end connections are manufactured with tight dimension tolerance and are validated for strength and connection integrity under extreme use conditions as well as for their ability to withstand prevalent sterilization methods including autoclaving.



1/2" HB



1/2" Single Stepped
Hose Barb



1/4" MNPT



1/4" SHB



Quick Connector



Male Luer Slip



3/8" Hose Barb



Female Luer Lock



1 1/2" Sanitary Flange



3/4" Sanitary Flange



1/2" MNPT



1" Hose Barb

Variety of end connections

Customized Connectivity

mdi ClariCap® PP filters are available in a wide range of end connections and are also customized to offer different inlet-outlet combinations to meet the unique connectivity needs for example, stainless steel components with sanitary flange connections are sometimes required to be connected to single use disposable systems through quick-connectors or hose barb connections.



1 1/2" Sanitary Flange
to 1/2" Barb Hose



1 1/2" Sanitary Flange
to 3/4" Sanitary Flange



ClariCap® with HighSecurity
1/2" hose barb connection

Linear Upscaling from R&D to Production Process

Datasheet

mdi offers a wide range of *ClariCap® 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 250 cm² to 15000 cm² hence process scaling can be facilitated without triggering additional validation studies for given process conditions. **mdi** provides complete documentation for each of the *ClariCap® PP* filters there by reducing the additional validation cost and time.



ClariCap® PP
1", 250cm²



ClariCap® PP
2", 500cm²



ClariCap® PP
5", 800cm²



ClariCap® PP
8", 1600cm²



ClariCap® PP
5" Large, 2500cm²



ClariCap® PP
10", 5000cm²



ClariCap® PP
20", 10000cm²



ClariCap® PP
30", 15000cm²

Filter Devices	EFA* (Nominal)	Hold up Volume
<i>ClariCap® PP 1"</i>	250cm ²	< 5ml
<i>ClariCap® PP 2"</i>	500cm ²	< 25ml
<i>ClariCap® PP 5"</i>	800cm ²	< 45ml
<i>ClariCap® PP 8"</i>	1600cm ²	< 60ml
<i>ClariCap® PP 5" Large</i>	2500cm ²	< 80ml
<i>ClariCap® PP 10"</i>	5000cm ²	< 150ml
<i>ClariCap® PP 20"</i>	10000cm ²	< 250ml
<i>ClariCap® PP 30"</i>	15000cm ²	< 350ml

***EFA: Effective Filtration Area**

Specifications

Small Capsule Filters

Datasheet

Construction

Membrane	Polypropylene
Support layers	Polypropylene
Plastic Parts	Polypropylene

Size

Size	1"	2"	5"	8"
Operational Radius (with Vent/ Drain)	30 mm	65 mm	65 mm	65 mm
Vent and Drain	¼" Hose Barb with Silicone "O" rings			

Operational

Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm ²)
Max. Differential Pressure	60 psi (4 Kg/cm ²) @ 30 °C
Sterilization By Autoclave	Autoclavable at 125°C for 30 minute, 30 cycles and it cannot be in-line steam sterilized

Assurance

Toxicity	Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics
Non Fiber Releasing	Passes test and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>
TOC and Conductivity	Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after specified WFI flush
Particle Release	The filtrate complies with USP <788> test for particulate matter in injections
Extractables with WFI	Passes NVR test as per USP <661>
Effect on WFI	Does not affect the quality of water (as specified in USP)
Indirect Food Additives	Comply with USFDA 21 CFR Part 177.1520
Oxidizable Substances	Passes test as per USP <1231>
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Specifications

Large Capsule Filters

Datasheet

Construction

Membrane	Polypropylene
Support layers	Polypropylene
Plastic Parts	Polypropylene

Size

Size	5"	10"	20"	30"
Operational Radius (with Vent/ Drain)	78 mm	78 mm	78 mm	78 mm
Vent and Drain	¼" Hose Barb with Silicone "O" rings			

Operational

Max. Operating Temperature	80 °C @ < 30 psi (2 Kg/cm ²)
Max. Differential Pressure	60 psi (4 Kg/cm ²) @ 30 °C
Sterilization By Autoclave	Autoclavable at 125°C for 30 minute, 30 cycles and it cannot be in-line steam sterilized

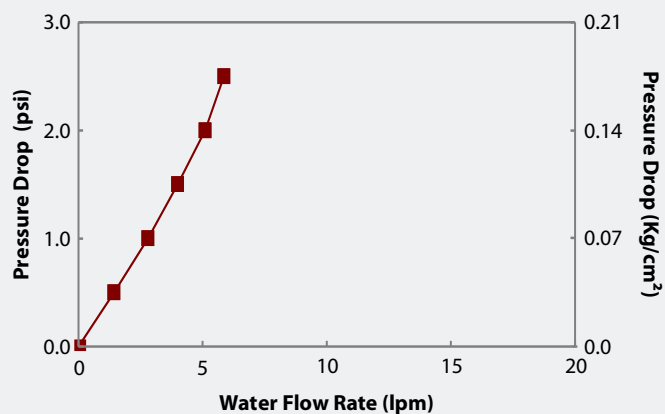
Assurance

Toxicity	Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics
Non Fiber Releasing	Passes test and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>
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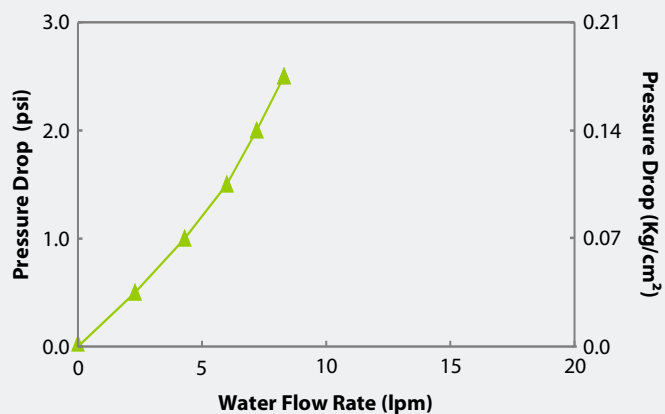
Typical Water Flow Rates

Datasheet

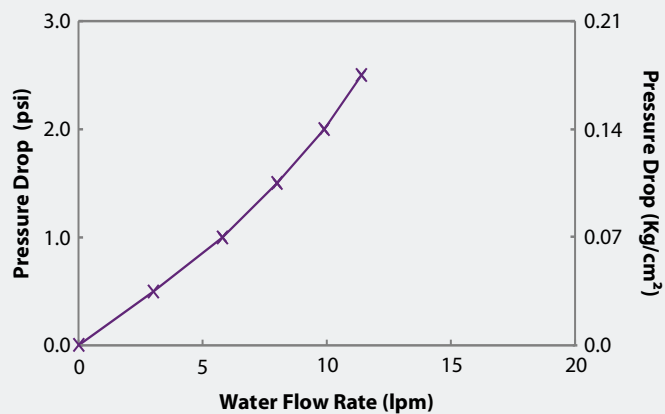
0.5µm ClariCap® PP, 5" Capsule Filter



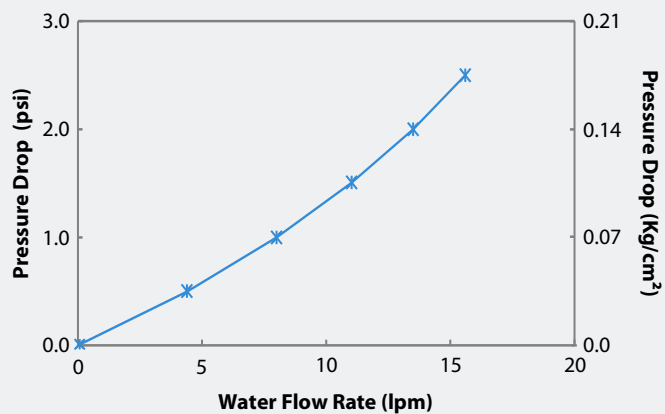
1 µm ClariCap® PP, 5" Capsule Filter



2.5µm ClariCap® PP, 5" Capsule Filter



5µm ClariCap® PP, 5" Capsule Filter

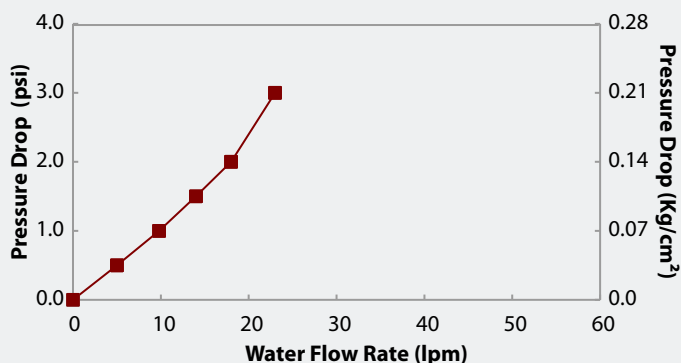


- 0.5 µm, 5 Inch Capsule Filters
- 1 µm, 5 Inch Capsule Filters
- 2.5 µm, 5 Inch Capsule Filters
- 5 µm, 5 Inch Capsule Filters

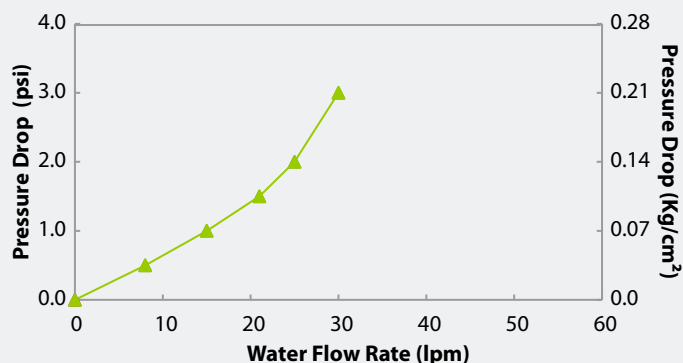
Typical Water Flow Rates

Datasheet

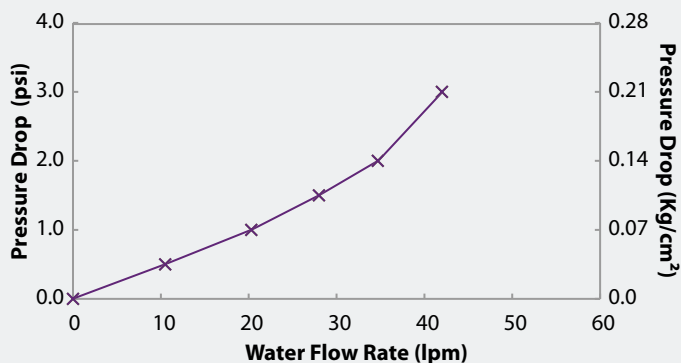
0.5µm ClariCap® PP, 10" Capsule Filter



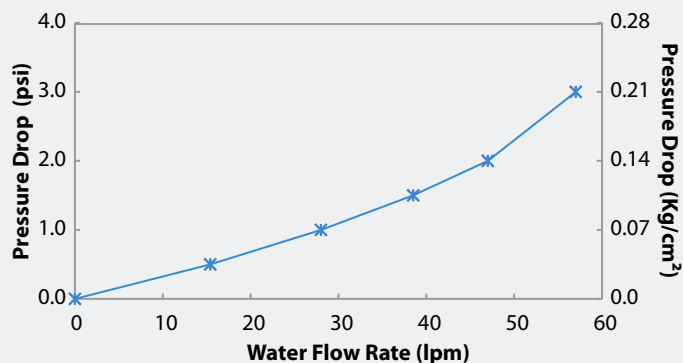
1 µm ClariCap® PP, 10" Capsule Filter



2.5µm ClariCap® PP, 10" Capsule Filter



5µm ClariCap® PP, 10" Capsule Filter



- 0.5 µm, 10 Inch Capsule Filters
- 1 µm, 10 Inch Capsule Filters
- 2.5 µm, 10 Inch Capsule Filters
- 5 µm, 10 Inch Capsule Filters

End Connection Type:

E: 1½" Sanitary Flange Connections

Ordering Information

Datasheet

ClariCap® PP Polypropylene Media Small Capsule filter

Type		Size		Pore Size		Inlet/Outlet		X	X	Sterility		Pack Size	
	Code		Code		Code		Code				Code		Code
ClariCap® PP	DOLX	1"	51	0.5 µm	04	¼" SHB	A			Non Sterile	1	1	01
		2"	52	1 µm	05	¼" MNPT (18 TPI)	B						
		5"	53	1.2 µm	10	¼" BSP (19 TPI)	M						
		8"	57	2.5 µm	06	¼" BSP (19 TPI) with O-ring	P						
				3 µm	16	¼" BSP	F						
				5 µm	07	½" MNPT	C						
				6 µm	25	½" Hose Barb	D						
				10 µm	08	1½" Sanitary Flange	E						
				20 µm	11	¾" Sanitary Flange	S						
						Quick Connector	J						
						½" Single Step Hose Barb	Q						
						Female Luer Lock	U						
						Male Luer Slip	W						
						⅜" Hose Barb	N						

Example:

DOLX	57	04	DD	X	X	1	01
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Inlet/Outlet Connections Available

Inlet/Outlet	Size/Length			
	1"	2"	5"	8"
¼" Stepped Hose Barb	√	√	√	√
½" Single Step Hose Barb	X	√	√	√
½" Hose Barb	√	√	√	√
1½" Sanitary Flange	√	√	√	√
¾" Sanitary Flange	√	√	√	√
Quick Connector	√	√	√	√
½" MNPT	X	√	√	√
¼" MNPT (18 TPI)	√	√	√	√
¼" BSP (19 TPI)	Inlet Only	X	X	X
¼" BSP (19 TPI) with O-ring	Inlet Only	X	X	X
¼" BSP	Inlet Only	√	√	√
Female Luer Lock	√	√	√	√
Male Luer Slip	Outlet Only	X	X	X
⅜" Hose Barb	√	√	Outlet Only	X
⅝" Hose Barb	√	√	√	√
¾" Single Step Hose Barb	√	√	√	√

Dimension (Length) (in mm)

Dimensions (in mm)	Small Capsule Filters			
End Connections	1"	2"	5"	8"
¼" SHB I/O	94	122	172	223
¾" Sanitary Flange Inlet I/O	85	104	155	206
Quick Connector	100	113	164	218
1½" Sanitary Flange I/O	92	112	164	216
½" Hose Barb I/O	90	112	162	214
½" Single Step Hose Barb I/O	-	115	165	218
1½" Sanitary Flange Inlet ½" Single Step Hose Barb Outlet	-	112	165	216
3/8" Hose Barb I/O	-	115	167	217
¼" Single Step Hose Barb I/O	90	106	160	212
Operational Radius	40	65	65	65

Ordering Information

Datasheet

ClariCap® PP Polypropylene Media Large Capsule filter

Type		Size		Pore Size		Inlet/Outlet		X	Inline/ T-Line		Sterility		Pack Size	
	Code		Code		Code		Code			Code		Code		Code
ClariCap® PP	LOLX	5"	53	0.5 µm	04	½" Single Step Hose Barb	Q		Inline	X	Non Sterile	1	1	01
		10"	54	1 µm	05	1½" Sanitary Flange	E		T-Line*	T				
		20"	55	1.2 µm	10	¾" Sanitary Flange	S							
		30"	56	2.5 µm	06	¾" Hose Barb	I							
				3 µm	16	1" Hose Barb	Z							
				5 µm	07									
				6 µm	25									
				10 µm	08									
				20 µm	11									

Example:

LOLX	54	04	EE	X	T	1	01
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*T-line is not available in 5" Capsule filter

*T-line Capsule Filter are available with 1½" Sanitary Flange I/O Connections Only

Inlet/Outlet Connections Available

Inlet/Outlet	Inline				T-Line		
	5"	10"	20"	30"	10"	20"	30"
½" Single Step Hose Barb	√	√	√	√	X	X	X
1½" Sanitary Flange	√	√	√	√	√	√	√
¾" Sanitary Flange	√	√	X	X	X	X	X
¾" Hose Barb	√	√	√	√	X	X	X
1" Hose Barb	X	√	√	√	X	X	X

Dimension (Length) (in mm)

End Connections	Inline Capsule Filters				T-line Capsule Filters		
	5"	10"	20"	30"	10"	20"	30"
1½" Sanitary Flange I/O	205	330	600	855	340	580	840
¾" Sanitary Flange I/O	214	335	x	x	x	x	x
½" Single Step Hose Barb I/O	218	336	630	890	x	x	x
1½" Sanitary Flange Inlet ½" Hose Barb Outlet	212	334	620	870	x	x	x
¾" Hose Barb I/O	211	332	634	878	x	x	x
1" Hose Barb I/O	x	405	635	895	x	x	x
Operational Radius	80	80	80	80	80	80	80

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