mdi
Membrane Technologies

Data Sheet

AseptiSure® HL

Large Area Hydrophilic Polyethersulfone (PES) Membrane Cartridge Filters

Pharmaceutical and Biopharmaceutical processing requires sterilizing grade microfiltration at multiple stages to meet specific process requirements.

Processes managers are continuously looking for microfiltration solutions for large volume parenteral as well as difficult to filter process fluids. The key requirements are:

- High flow rates, high througputs
- High throughputs to achieve process economy
- Absolute retentions for higher sterility assurance

mdi *AseptiSure® HL* large area PES membrane cartridge filters offer very high flow rates to meet and exceed process efficiency requirements in large volume parenterals and in case of difficult to filter solutions.

mdi *AseptiSure® HL* filters are validated for key performance parameters such as retention efficiency, chemical compatibility, extractables, heat stability and flow rates.

AseptiSure® HL

PES Membrane Cartridge Filters

Datasheet

mdi *AseptiSure® HL* 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 flow rates
- High throughputs
- Long service life
- Comply with USP <788> for particulate matter in injections
- Non-toxic material of construction
- Absolute retention
- 100% integrity tested
- Bioburden maintained below 1000 cfu/device
- Endotoxin level certified to be <0.25 EU/ml
- Unique identification number is laser etched on each filter
- Individual certificate of quality for each device
- Sterilizable by Autoclaving/Steaming in place (SIP)

Applications

Sterilizing filtration of:

- Large Volume Parenterals
- Difficult to filter solutions

Validation Services

The regulatory requirements emphasize on the need to validate the efficacy of the filter with drug product under simulated worst-case conditions of use.

mdi provides validation services supported by customized validation protocols and world class test facilities to assist you in filter validations with your specific drug product.

Quality Assurance

Datasheet

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 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.

Validated for Microbial Retention

Integrity test data have been correlated to actual microbial retention with *B.diminuta* (ATCC 19146) as per ASTM F838 to establish acceptable integrity test values.

Samples from each lot are subjected to microbial challenge test before final lot release.

100% Integrity Tested

Each *AseptiSure® HL* 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

AseptiSure® HL filters are validated for low protein binding to ensure minimal active ingredient losses when used for filtration of high value proteins.

Pressure, Temperature Endurance

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

Extractables

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

AseptiSure® HL filters are validated to exhibit low extractables under harsh extraction conditions.

Bioburden Testing

AseptiSure® HL bioburden is tested as per ISO 11737-1 and assured to be <1000 cfu/device.

Endotoxin Testing

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

Total Traceability

AseptiSure® HL 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

AseptiSure® HL 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

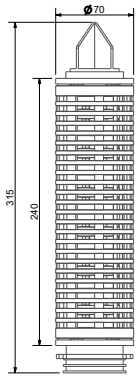
- Complies with USFDA 21 CFR 210.3(b)(6) for fiber release
- Complies with USFDA 21 CFR 177.1520 for fractional dissolution
- Materials of construction tested for toxicity as per Biological Reactivity Tests, In-vivo, USP <88> for class VI Plastics
- Complete filter devices tested for cytotoxicity as per Biological Reactivity Tests, In-vitro, USP <87>

Adapters and Dimensions

Datasheet

Standard Cartridge Filters

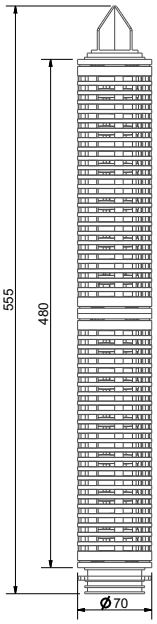
10" Cartridge Filter- 7P Adapter with Fin (A0)



Total Length : 315 mm

Diameter : 70 mm

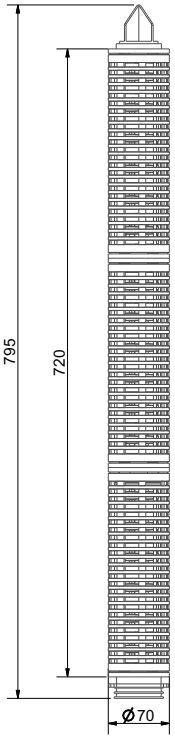
20" Cartridge Filter- 7P Adapter with Fin (A0)



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	**10”**	**20”**	**30”**
7P	√	√	√
7P without Fin	√	√	√
28 with Fin	√	√	√
‘O’	√	√	√

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

Datasheet

Scientists are concerned about filter fluid interaction impacting the stability, purity, strength etc. of the drug product, and they take a keen interest in filter selection at the formulation development stage itself. Although preliminary compatibility data support initial filter selection, for stability studies detailed filter validations are required to provide enough documented evidence to justify specific filter use.

A critical requirement that needs to be addressed at this stage is of scalability from pilot scale to full scale production processes.

mdi offers a wide range of *AseptiSure® HL* 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 8000 cm^2 to 24000 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 *AseptiSure® HL* filters there by reducing the additional validation cost and time.

***AseptiSure® HL*, 10"**
EFA: 8000 cm^2

***AseptiSure® HL*, 20"**
EFA: 16000 cm^2

***AseptiSure® HL*, 30"**
EFA: 24000 cm^2

***EFA: Effective Filtration Area**

Specifications

Standard Cartridge Filters

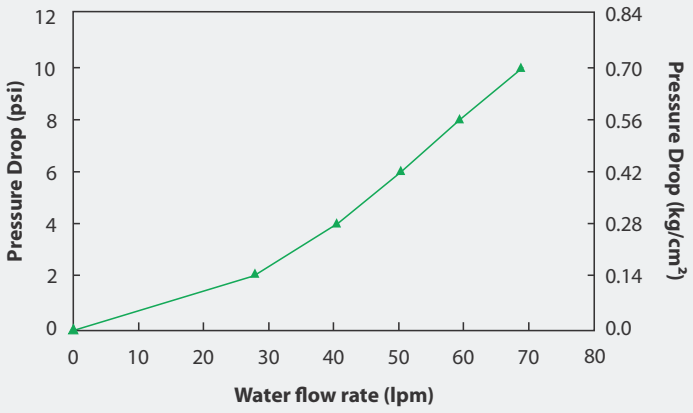
Datasheet

Construction				
Membrane		Hydrophilic PES		
Support Layers		Polyester		
Plastic Parts		Polypropylene		
O rings		Silicone		
		Viton		
		EPDM		
		FEP Encapsulated Viton		
Integrity Testing / Retention				
Pore Size		0.2 µm		
Bubble Point with Water		≥ 50 psi (3.52Kg/cm^2)		
Air Diffusion Flow with Water	10″ Filter	≤ 35 ml/min @ 37 psi (2.6 Kg/cm^2)		
	20″ Filter	≤ 70 ml/min @ 37 psi (2.6 Kg/cm^2)		
	30″ Filter	≤ 105 ml/min @ 37 psi (2.6 Kg/cm^2)		
Microbial Retention		LRV >7 for *Brevundimonas diminuta* (ATCC 19146) per cm^2		
Size				
Size		10″	20″	30″
Effective Filtration Area (Nominal)		8000cm^2	16000cm^2	24000cm^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/In-line steam sterilizable at 135 ° C for 30 minutes, 25 cycles		
Assurance				
Toxicity		Passes Biological Reactivity tests, In Vivo, as per USP <88> for Class VI plastics		
Cytotoxicity		Passes Biological Reactivity tests, In Vitro, USP <87> for cytotoxicity		
Bacterial Endotoxin		Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>		
Bioburden		Bioburden level is < 1000 cfu/filter device as per ISO 11737-1		
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		
TOC and Conductivity		Meets the WFI requirements of USP for TOC <643> and Conductivity <645> after flush with specified volume		
Extractables with WFI		Passes NVR test as per USP <661>		
pH Compatibility		Compatible with pH range of 1-10		
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		

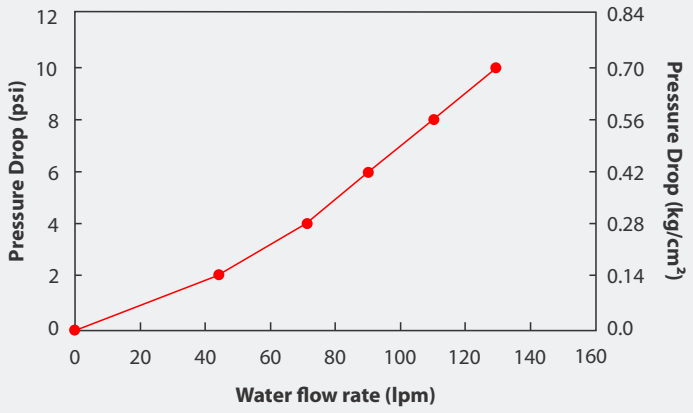
Typical Water Flow Rates
Standard Cartridge Filters

Datasheet

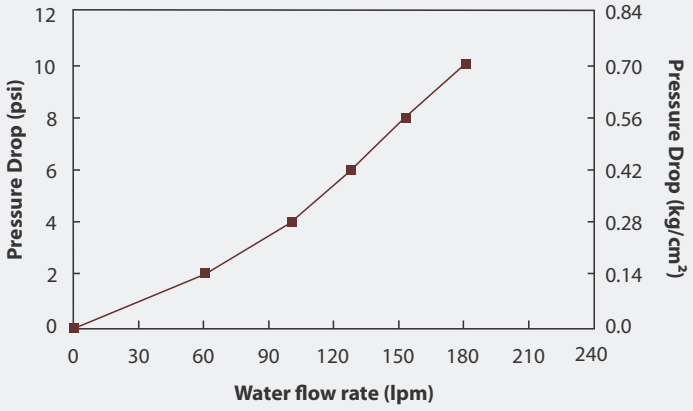
0.2µm *AseptiSure® HL*, 10" Standard Cartridge Filters



0.2µm *AseptiSure® HL*, 20" Standard Cartridge Filters



0.2µm *AseptiSure® HL*, 30" Standard Cartridge Filters



Ordering Information

AseptiSure® HL PES Membrane Standard Cartridge Filter

Type	
	Code
AseptiSure® HL	CPH0

Size	
	Code
10″	64
20″	65
30″	66

Pore Size	
	Code
0.2µm	01

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:

CPH0	64	01	A1	SS	1	01

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

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