mdi
Membrane Technologies

0.2µm *AseptiSure NN* Nylon-66 Membrane Cartridge Filters

mdi *Aseptisure NN* Nylon-66 membrane cartridge filters are sterilizing grade filters offering absolute retention and wide chemical compatibility. These filters incorporate two layers of nylon membranes of the same pore size for extra reliability.

Special Features

- Absolute retention
- Minimal extractables
- High heat resistance
- Wide chemical compatibility
- Biologically inert
- Hydrophilic
- Total Traceability :
  Unique identification number is laser etched on each filter

Microbially Validated as per ASTM F 838-05
Complies with USDFA 21 CFR 210.3(b)(6)
Meets and Exceeds USDFA 21 CFR 177.1520

Applications

- Sterilization of compatible solvents and chemicals
- Sterilization of disinfectants in pharmaceutical labs and process areas
- Sterilizing filtration of pharmaceutical, aqueous and non aqueous solutions

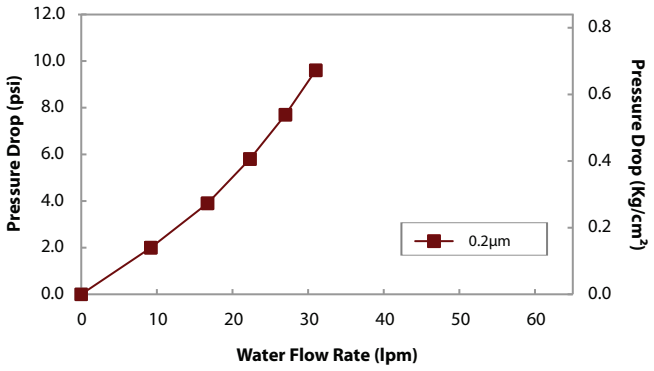
Specifications

Construction				
Final Filter Pore Size	0.2µm			
Prefilter Pore Size	0.2µm			
Membrane	Nylon-66			
Support Layers	Polyester			
Body and Core	Polypropylene			
Integrity Testing / Retention				
Air Diffusion Flow for 10" Cartridge filters (with 50% IPA Wetted)	< 15 ml/min @ 16 psi (1.12Kg/cm^2)			
Microbial Bacterial Retention (LRV >7 for)	Brevundimonas diminuta (ATCC 19146) per cm^2			
Size				
Size	5"	10"	20"	30"
Effective Filtration Area (Nominal)	3000cm^2	6000cm^2	12000cm^2	18000cm^2
Operational				
Max. Operating Temperature	80 °C @ < 2 Kg/cm^2 (30 psi)			
Max. Differential Pressure	< 3.5Kg/cm^2 (50 psi) @ 25°C			
Reverse Pressure	< 0.7 Kg/cm^2 (10 psi) @ 25 °C			
Sterilization	Autoclavable/In-line Steam Sterilizable at 121 °C for 30 minutes			

Assurance	
Toxicity	Passes Biological reactivity test, In Vivo, as per USP <88> for Class VI plastics
Bioburden	Bioburden level is < 1000 cfu/filter device as per ANSI/AAMI/ISO 11737-1 : 1995
Bacterial Endotoxin	Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>
Non Fiber Releasing	Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release
Oxidizable Substances	Passes test as per USP <1231>
Particle Shedding	The filtrate complies with USP <788> test for particulate matter in injections
TOC/Conductivity at 25 °C	Meets the WFI requirements of USP <643> for Total Organic Carbon and USP <645> for Water Conductivity after a specified volume of purified water flush
Indirect Food Additive	All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520
Good Manufacturing Practice	These products are manufactured in a facility which adheres to Good Manufacturing Practices.
Quality Management System	ISO-9001 Certified
USFDA	DMF No. 015554

Water Flow Rates

AseptiSure NN, 10" Cartridge Filters



Ordering Information

Type	
	Code
Aseptisure NN (0.2 µm Upstream)	CPN1

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

Pore Size	
	Code
0.2 µm	01

Adaptor	
	Code
7P	A0
7P without fin	A1
'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

CPN1	53	01	A0	SS	1	01

***Size 5" are available in Code A0 (7P) and A1 (7P without fin) only**

****FV is available in Code A0 (7P) only**

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