Duredunty® Filter Cartridges

Double-layer PES Membrane·Sterile Liquid Filter

Duredunty® Filter Cartridges use a unique double-layer PES membrane which provides excellent reliability in filtration and sterilization. They are designed for the filtration of a broad range of pharmaceutical products and the removal of particles, cysts, oocysts and bacteria in aqueous filtration filtration application, while providing superior flow rates and high particle removal efficiency when compared to other sterilizing grade filter cartridges.

Features and Benefits

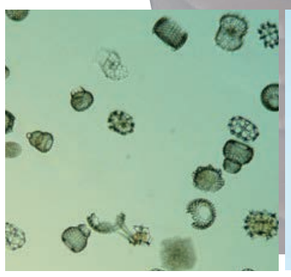
- Double-layer hydrophilic PES membrane which requires no pre-wetting
- Asymmetric pre-filter layer provides longer service life and lower filtration cost
- Broad chemical compatibility (pH 1-14)
- Provides 10x the safety when compared to normal PES filters
- Design allows for multiple autoclave cycles (up to 30) and extended use

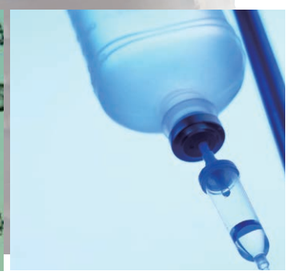
Quality Standards

- Bacterial quantitative retention of 10^7 CFU/cm^2 Brevundimonas Diminuta(ATCC 19146) according to ASTM F838 methodology .
- 100% Integrity testing in manufacturing .
- Each filter is fully traceable with unique serial number .
- Manufactured in a facility which adheres to ISO 9001:2015 Practices .
- Full Regulatory Compliance with following :
  - •Bacterial Endotoxin :Aqueous extraction of autocalved filter contains <0.25 EU/ml as determined by Limulus Amebocyte Lysate (LAL),USP<85>.
  - •Non-fiber Releasing :Component materials meet the criteria for a " Non-fiber-releasing filter " as defined in 21 CFR 210.3(b)(6).
  - •Component Material Toxicity :Meet the requirement of USP <87> In Vitro Cytotoxicity Test ; Meet the Criteria of USP<88> Biological Reactivity Test for Class VI-121℃ plastics
  - •TOC/Conductivity at 25 ℃: Autoclaved filter effluent meet the USP<643> for Total Organic Carbon and USP<645> for Water Conductivity per WFI requirements after a UPW flush of specified volume .
  - •Particle Shedding : Autoclaved filter effluent meet the USP<788>for large volume Injections .
  - •Indirect Food Additive: All component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177-182 , and EU framework regulation [1935/2004/EC].

Typical Application

- Biological Vaccines
- Blood Products
- LVP and SVP
- Lyophilization Freeze-dried Powder
- Ophthalmic Solutions
- Sterile API

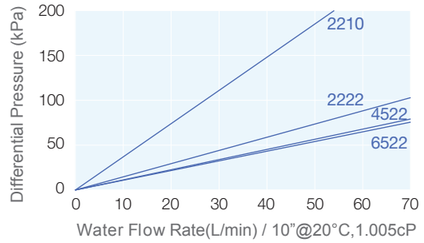




Materials of Construction

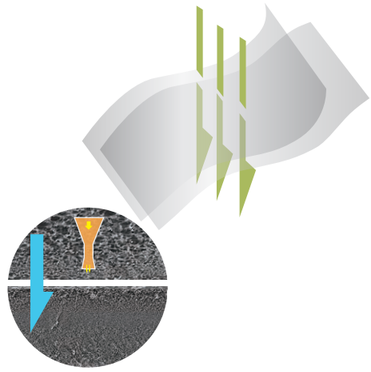
Filter Media	Double-Layer PES Membrane (Asymmetric PES + Symmetric PES)
Cage/Support	Polypropylene
Core/End Cap	Polypropylene

Flow Rate Characteristics



Operating Conditions

Max. Operating Pressure	6.9 bar (100 psi) at 25 °C 4.0 bar (58 psi) at 60 °C 2.4 bar (35 psi) at 80 °C
Max. Differential Pressure	Forward 6.9 bar (100 psi) at 25 °C 4.0 bar (58 psi) at 60 °C 2.4 bar (35 psi) at 80 °C Reverse 3.0 bar (44 psi) at 25 °C 1.0 bar (15 psi) at 80 °C
Effective Filtration Area	0.6m² / Φ 69-10 inch



Sterilization

Inline Steam Sterilization	up to 100 cycles (135°C for 30min< 0.3 bar per cycle)
Autoclave	up to 200 cycles (130°C for 30min per cycle)

Integrity Test Data

Bubble Point	⩾0.34 MPa (water) ,0.45+0.22μm
Diffusion Flow	⩽25 ml/min/10" @ 0.275MPa (water),0.45+0.22μm

Ordering Information

DPSDDT	Removal Ratings	End Cap	Nominal Length	Seal Material	-P
	2210=0.22μm+0.1μm	**HSF**=226 /Fin (PBT Insert)	**05**=5"	**S**=Silicone	
	2222=0.22μm+0.22μm	**HSC**=226 /Flat (PBT Insert)	**10**=10"	**E**=EPDM	
	4522=0.45μm+0.22μm	**HTF**=222 /Fin (PBT Insert)	**20**=20"	**V**=Viton	
	4545=0.45μm+0.45um	**HTC**=222 /Flat (PBT Insert)	**30**=30"	**P**=PFA/Viton	
	6545=0.65μm+0.45μm	**DOE**=Double Open End	**40**=40"		