FluoroPV[®] Filter Cartridges PVDF Membrane·Sterile Liquid Filter

FluoroPV[®] Filter Cartridges are composed of a unique hydrophilic polyvinylidene fluoride (PVDF) membrane characterized by low extractable and protein binding. They are suitable for the sterilized filtration of pharmaceutical liquids including ophthalmic liquids, biological and other diluted preservative solutions.

Features and Benefits

- · Low extractable and protein binding
- Broad chemical compatibility and temperature resistance
- Excellent durability proven by testing forward/reverse pulse up to 100x

Quality Standards

- Bacterial quantitative retention of 107 CFU/cm2 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 Amebcyte 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 C plastics •TOC/Conductivity at 25 C: 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.

Typical Applications

- Antibiotics
- Aggressive Solvents
- Biological Agents
- Blood Products
- Cold and Hot WFI

Chemicals

- Ophthalmic Solutions Sanitizing Agents



Materials of Construction

	Filter Media	LHPVND: Single-Layer Hydrophili DLHPVNDR: Double-Layer Hydro	
	Support	Polypropylene	
	Cage/Core/End Caps	Polypropylene	

Operating Conditions

6.9 bar (100 psi) at 25 °C 4.0 bar (58 psi) at 60 °C 2.4 bar (35 psi) at 80 °C	
Forward 6.9 bar (100 psi) at 4.0 bar (58 psi) at 6 2.4 bar (35 psi) at 8 Reverse 3.0 bar (44 psi) at 2 1.0 bar (15 psi) at 8	
0.58m²/ Φ 69-10 inch	

Sterilization

Inline Steam Sterilization (LHPVND & DLHPVNDR)	Up to 100 forward cycles and (135 °C for 30 min < 0.3 bar
Autoclave (LHPVND & DLHPVNDR)	up to 400 cycles (130°C for 30

Integrity Test Data

Bubble Point	BP : \geq 0.32 MPa(water), LHF
Diffusion Flow	DF : < 20 ml/min/10"@ 0.28

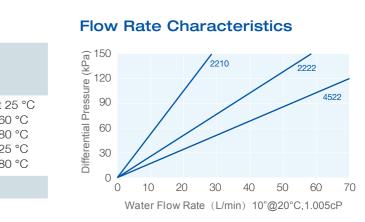
Ordering Information

LHPVND		End Cap		Seal Material	-P
[Single-Layer]	0010 =0.10µm	HSF=226 /Fin (PBT Insert)	05 = 5"	S =Silicone	
	0022=0.22µm	HSC=226 /Flat (PBT Insert)	10 =10"	E =EPDM	
	0045 =0.45µm	HTF=222 /Fin (PBT Insert)	20 =20"	V =Viton	
	0065 =0.65µm	HTC=222 /Flat (PBT Insert)	30 =30"	P =PFA/Viton	
	0100 =1.0µm	DOE=Double Open End	40 =40"		

DLHPVNDR 2222=0.22+0.22µm [Double-Layer]

2245=0.22+0.45µm 6545=0.65+0.45µm 2210=0.22+0.1µm 4545=0.45+0.45µm 6522=0.65+0.22µm 6510=0.65+0.1µm 4510=0.45+0.1µm





50 reverse cycles per cycle). Omin per cycle)

IPVND (0.22 µm) 28 MPa, LHPVND (0.22 µm)



Cobetter Pharmaceutical Industry Filtration Solutions