## Hall Pyke



**Membrane Filtration** 

## Superdura SLHPF Hydrophillic PTFE

The SMART choice for filtration

#### Super-Dura® Filter Cartridges

Hydrophilic PTFE Membrane · Sterile Liquid Filter

**Super-Dura**® Filter Cartridges are designed for the majority of pharmaceutical liquids, but especially for solvent-containing liquids and ophthalmic solutions.

These filters are composed of a hydrophilic PTFE membrane which provides excellent chemical and heat tolerance.

#### **Features and Benefits**

- · Hydrophilic PTFE membrane which requires no pre-wetting
- · Excellent chemical compatibility especially for solvent-containing liquids
- Minimal preservative binding in ophthalmic solutions
- · Clean membrane with very low gravimetric extractable

#### **Quality Standards**

- Bacterial quantitative retention of 10<sup>7</sup> CFU/cm<sup>2</sup> 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.
- $\cdot \ \mathsf{Particle \ Shedding:} \ \mathsf{Autoclaved \ filter \ effluent \ meet \ the \ USP<788> for \ large \ volume \ Injections.}$
- · 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**

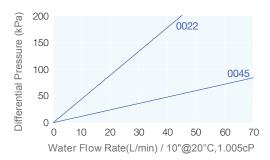
- Antibiotics
- · LVP & SVP
- · Large Batch Solutions
- · Ophthalmic Solutions
- Disinfectants and Sanitizing Agents



#### **Materials of Construction**

Filter Media	SLHPF Single-Layer Hydrophilic PTFE Membrane		
	DLHPF	Double-Layer Hydrophilic PTFE Membrane	
Support	Polypropylene		
Core/Cage/End Caps	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	0.65m <sup>2</sup> / Φ 69-10 inch	

#### **Sterilization**

Inline Steam Sterilization	up to 10 cycles (135°C for 30min< 0.3 bar per cycle),SLHPF up to 35 cycles (135°C for 30min< 0.3 bar per cycle),DLHPF
Autoclave	up to 120 cycles (130°C for 30min per cycle)

#### **Integrity Test Data**

Bubble Point	BP: ≥ 0.32 MPa (water), DLHPF(0.22 µm)
Diffusion Flow	DF: ≤ 30 ml/min/10"@ 0.22 MPa, DLHPF(0.22 um)

#### **Ordering Infomation**

SLHPF	Removal Ratings	End Cap	Nominal Length	Seal Material -P
[Single-Layer]	<b>0022</b> =0.22µm	HSF = 226/Fin (PBT Insert)	<b>05</b> = 5"	S = Silicone
	<b>0045</b> =0.45μm	HSC = 226/Flat (PBT Insert)	<b>10</b> = 10"	<b>E</b> = EPDM
	<b>0100</b> = $1.0 \mu m$	HTF = 222/Fin (PBT Insert)	<b>20</b> = 20"	V = Viton
		HTC = 222/Flat (PBT Insert)	<b>30</b> = 30"	$\mathbf{P} = PFAViton$
		DOE = Double Open End	<b>40</b> = 40"	
<b>DLHPF</b> [Double-Layer]	<b>2222</b> = 0.22+0.22 µm			
	<b>4545</b> =0.45+0.45μm			

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