

## PF-N6

Positive Zeta Nylon66 Membrane · Sterile Liquid Filter



Ultrafilter BeLux Beta Solutions B.V. Begoniastraat 36 - 9810 Nazareth - Belgium

Tel: +32 (0)9 324 88 63 e-Mail: info@ultra-filter.be - www.ultra-filter.be

### PF-N6

#### PF-N6:

Ultrafilter PF-N6 FilterCartridges are composed of an inherently hydrophilic Nylon 66 membrane. It's specifically designed for bio-burden reduction and the final filtration of a wide range of pharmaceutical and biological solutions. A modified Nylon 66 membrane with positive-charged Zeta particles is available, which provides enhanced retention of fine particles such as endotoxins.

#### **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
  - 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, and EU framework regulation [1935/2004/EC].

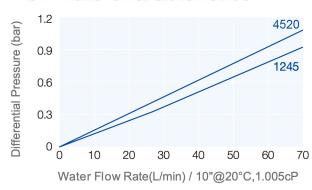
#### **FEATURES AND BENEFITS:**

- Inherently water wettability
- Nylon66 filter removes endotoxins through the formation of positive-charged Zeta particles
- High bubble point ensures a more reliable retention efficiency
- Low pressure drops and high flow rates
- Longer service life

#### **APPLICATIONS:**

- Buffer Solutions
- WFI
- LVP & Antibiotics

#### **Flow Rate Characteristics**





Begoniastraat 36 - 9810 Nazareth - Belgium Tel: +32 (0)9 324 88 63 e-Mail: info@ultra-filter.be - www.ultra-filter.be

# PF-N6

### **Technical Data:**

MATERIALS OF CONSTRUCTION		
Filter Medium	Nylon 66 membrane	
Support	Polypropylene	
Cage/Core/End Caps	Polypropylene	
Adapter Internal Support	PBT	
0-rings	Silicone,EPDM,Fluoroelastomer	

OPERATING CONDITIONS		
Maximum 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	
Bubble Point	BP: ≥3.0 bar (44 psi), air, 0.22µm BP: ≥1.2 bar (17 psi), air,1.2+0.45µm	
Diffusion Flow	DF: ≤16ml/min/10''@0.275Mpa, 0.22µm	
Inline Steam Sterilization	Up to 10 cycles (121°C for 30 min < 0.3 bar per cycle)	
Effective Filtration Area	0.58m²/ Φ 71-10 inch	

#### **ORDERING INFORMATION**

PF-N6

	REMOVAL	NOMINAL LENGTH	END CAP	SEAL MATERIAL
PF-N6SL	10 = 0.10 μm	5 = 5"	2 = Code 2	A = EPDM
	20 = 0.20 μm	1 = 10"	3 = Code 3	B = Silicone
	45 = 0.45 μm	2 = 20"	7 = Code 7	C = Viton
	10 = 1.00 μm	3 = 30"	8 = Code 8	G = PFA/Viton
		4 = 40"	MF = D0E	
PF-N6DL	1010 = 0.10 + 0.10 μm			
	2020 = 0.20 + 0.20 μm			
	4520 = 0.45 + 0.20 μm			
	1045 = 1.00 + 0.45 μm			
	1245 = 1.20 + 0.45 μm			



Ultrafilter BeLux

3

Beta Solutions B.V. Begoniastraat 36 - 9810 Nazareth - Belgium Tel: +32 (0)9 324 88 63 e-Mail: info@ultra-filter.be - www.ultra-filter.be