Microcap™ PNYPC

Pharmaceutical Grade Positively Charged Nylon 6.6 Pleated Membrane Capsules



MicrocapTM PNYPC capsule filters consist of a positively charged Nylon 6,6 membrane used for filtering aqueous and non-aqueous liquids that contain negatively charged contaminants.

Available in 0.10, 0.22, 0.45 and 0.65 μ m, MicrocapTM PNYPC filters are validated for bacteria retention to provide reliable sterile filtration performance.

The positive charge removes negatively charged biological contaminants such as endotoxin, virus and other cell fragments.

Depending on level of contaminant and flow rate, MicrocapTM PNYPC filters will typically exhibit > 3-log removal of endotoxin. This combination of functionality makes the PNYPC filter an excellent choice for pharmaceutical and bioprocessing applications.

Typical Applications

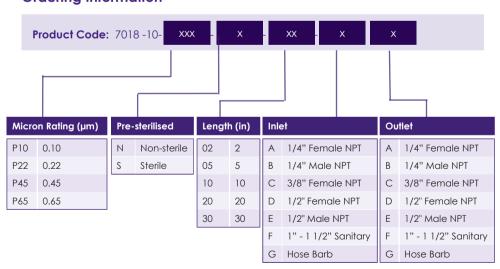
Microcap™ PNYPC filters are recommened for sterilising and endotoxin removal in:

- Process water
- Water for injection (WFI)

Features and Benefits

- Validated for use in pharmaceutical applications
- Integrity testable
- · Designed for minimal extractables
- Non-fibre releasing
- Low TOC levels
- USP Class VI approved
- Uses FDA complaint materials

Ordering Information



Specifications

Materials of Manufacture

Housing: Polypropylene

Filtration media: Positively Charaed Nylon 6,6 Membrane with

Polyester support

Media support: Polypropylene End caps: Polypropylene Centre core: Polypropylene Outer support cage: Polypropylene Sealing method: Thermal bonding

Validation

Microcap™ PNYPC filters are validated using test procedures that comply with ASTM F 838-15(ae1) protocols for the determination of bacterial retention in liquids. The challenge level is a minimum of 107 organisms per cm² of filter media. These capsules have > 7-log removal when challenged with the organisms listed below (0.10µm and 0.22µm meet the FDA definition of sterilising grade filters).

0.10µm: Brevundimonas diminuta 0.22µm: Brevundimonas diminuta 0.45µm: Serratia marcescens 0.65µm: Saccharomyces cerevisiae

Maximum Operating Parameters

Liquid Operational Pressure 5.52 bar at 20°C (80 psi at 68°F)

Gases Operational Pressure 4.14 bar at 20°C (60 psi at 68°F)

Operating Temperature (water) 43°C at 2.07 bar (110°F at 30 psi) **Reverse Differential Pressure** 3.45 bar at 20°C (50 psi at 68°F)

Recommended Changeout Pressure 2.41 bar (35 psi)

Sanitisation and Sterilisation

Autoclave* 121°C (250°F), 30 min, 25+ cycles

Chemical Sanitization Performed using industry standard concentrations of hydrogen peroxide, peracetic acid and other selected chemicals.

Filtration Area

Media	2"	5"	10"	20"	30"
Positively charged Nylon 6.6 Membrane	1.2 ft ²	3.3 ft ²	7.0 ft ²	14.0 ft ²	21.0 ft ²
	0.11m ²	0.31m ²	0.65m ²	1.30m ²	1.95m ²

Integrity Testing

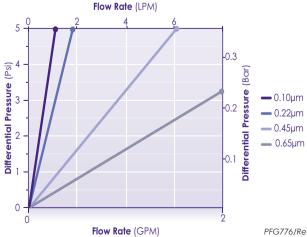
Pore Size	Diffusive Flow - Test Pressure *		Minimum Bubble Point *		
μm	Psi	Bar	Psi	Bar	
0.10	48	3.30	**	**	
0.22	35	2.41	50	3.5	
0.45	20	1.37	25	1.7	
0.65	15	1.03	19	1.3	

Diffusive Flow Specifications					
Length	2"	5"	10"	20"	30"
m/Lmin	≤ 2.1	≤ 6.3	≤ 15	≤ 30	≤ 45

^{*} For water wetted membrane

Clean Water Flow Rate

A 2" capsule with 1" sanitary inlet and outlet point, exhibits the flow-ΔP characteristics indicate below, for solutions with a viscosity of 1 centipoise.



^{*} Note: PNYPC capsules are not designed for steam-in-place (SIP).

^{**} Test pressure exceeds operational limits of capsule filters. Use the Diffusive Flow Test method.