

Certificate of Quality Hydrophilic PES PAA

Product No:PAA-0022-R20SP
Lot No: MA114690001
Pore Size:0.22um
Manufacture Date:2025-08-15

This document certifies to the product was manufactured by
Darly in a facility which refers to current Good Manufacturing
Practices (cGMP).

This product is developed, produced and distributed according to
management system that is certified for compliance with ISO9001.

Quality Assurance Criteria

The following is checked on a regular basis:

Biosafety

All materials meet the criteria of the USP <88> Reactivity Test for
Class VI Plastics.

Bacterial Retention

Finished product has been sampled for microbiological challenge
tests, as described in Validation Guides and correlated to ASTM
Standard Test Method F838-05, and meets the requirements of the
FDA Guideline on Sterile Drug Products Produced By Aseptic
Processing (June 1987).

Non-Fiber Releasing

The product meets the criteria for a "non-fiber releasing" filter
as defined in 21 CFR 210.3(b)(6).

Indirect Food Additive

All components materials meet the FDA Indirect Food Additive
requirements cited in 21 CFR 177-182. All components
materials meet the requirements of the EU framework
regulation [1935/2004/EC] regarding materials and articles
intended to contact food.

Multiple Sterilization Cycles

SIP:30cycles of 30min,125°C,ΔP≤30kpa

Autoclave:30cycles of 30min,125°C

Bacterial Endotoxins

A filter aqueous extraction contains less than 0.25EU/ml by the
Limulus Amebocyte Lysate (LAL) test.

TOC & Conductivity

Meets the current USP and CHP requirements under Purified
Water after flushing.

Gravimetric Extractable

The extractable level was not more than 20mg per 10 inch
cartridge after 24 hours in ASTM Type 1 reagent-grade water
at controlled room temperature.

Maximum Differential Pressures

Forward: 4.0 bar at 20°C;

Forward: 2.0 bar at 80°C.

Lot Release Criteria

Filter samples from this manufacturing lot underwent
the following tests.

100% Integrity Testing

Each filter has been tested and released by quality
assurance to the following specification:

Integrity Test Standard (20°C)

Bubble Point (BP):≥3.2bar

Forward Flow (FF):≤ 25ml/min@2.76bar10"



Quality Manager

Darly®

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