

Certificate of Quality

Hydrophilic PES_PAA

Product No:PAA0022R20S
Lot No: MO091459001
Pore Size:0.22um
Manufacture Date:2024-12-10

This document certifies to the product was manufactured by Darlly 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] regrading 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):≥ 3.2mbar
Forward Flow (FF):≤ 25ml/min@2.76bar10"



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