

Certificate of Quality Hydrophobic PTFE PTB

Product No:PTB-0022-R-10-SP

Lot No: MO087086001

Filter Size:0.22um

Manufacture Date:2024-10-21

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

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

Quality Assurance Criteria

The following is checked on a regular basis:

Safety

The materials meet the criteria of the USP <88> Reactivity Test for
Polyethylene VI Plastics.

Material Retention

The 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:150cycles of 30min,135°C,ΔP≤30kpa

Autoclave:150cycles of 30min,135°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):≥ 1.1bar 60%IPA:40%Water

Water Intrusion Test (WIT):≤ 1ml/min2.76bar10"

Quality Manager:



Darlly®
TOTAL FILTRATION SOLUTIONS

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