

Certificate of Quality Assurance

Membrane Solutions
Quality Assurance

Product Information

Part Number:	C150TCAPESB020
Lot Number:	337023105
Pore Size:	0.2µm
Filtration Area:	0.10 m ²
Inlet/Outlet Type:	1" Tri-clamp
Filter Media:	Sterilizing Grade PES
Capsule Shell:	PP
Core:	PP
Vent/Drain:	1/4" Hosebarb

Quality Management System

The development, production, and testing processes of this product conform to the relevant requirements of the ISO9001 quality management system.

Quality Assurance Criteria

This product was designed and manufactured to meet the following conditions, which are verified by testing on an audit basis:

Bacterial Retention

The samples were tested according to ASTM F838.

Challenge Microorganism	LRV/cm ²
B.diminuta	>7

Biosafety

All materials used in this product meet the requirements of Class VI plastic listed in USP <88>.

Indirect Food Additive

All materials used in this product meet the indirect food additive requirements cited in 21CFR 177 and EU 1935/2004/EC.

Non-Animal Origin Statement

Based on the information from our supplier, all polymers used in the manufacturing of this product were not animal origin.

Non-Fiber Releasing

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

Particle Shedding

The samples after flushed with 1L/10" DI water released particulate matters in quantities met the requirements of "Large Volume Injections for Single Dose Infusion" cited in USP<788>.

Extractables

The samples were immersed in DI water for 24 hours at 25°C and the extractable level was ≤ 40 per 10".

TOC and Conductivity

The TOC of flushing water was ≤ 0.5mg/L and the conductivity was ≤ 5.1 µs/cm at 25°C.

Bacterial Endotoxins

The samples were flushed with 1L/10" endotoxin free water and the aqueous extraction contains ≤ 0.25 EU/mL as determined by the LAL test cited in USP<85>.

Sterilization Cycles

The samples can maintain integrity after 5 cycles autoclaved of 30 minutes at 124 °C.

Hydraulic Stress

The samples can maintain integrity after the following operations.

Maximum operation temperature	80°C
Maximum Operating Pressure	Liquid: 6.0 bar (87 psi) @ 25°C Air: 4.1 bar (60 psi) @ 25°C
Max. Forward Differential Pressure:	5.2 bar @ 25°C
Max. Reverse Differential Pressure:	2.1 bar @ 25°C

Lot Release Criteria

This manufacturing lot was sampled, tested and released by Quality Assure based on the following tests:

Integrity Testing in Manufacturing

Each filter must pass the following integrity test and comply the threshold value that correlated to the bacterial challenge test.

Gas Source: compressed air

Wetting Liquid: DI water

Min. Bubble Point@ 25°C	3.3bar
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Tested By: Vita 02-18-2025

QC Technician