

Certificate of Quality

The Polyethersulfone Membrane Cartridge Filters have been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

AseptiSure HSPES Membrane Cartridge Filters

Catalog No. : CPHX5401A0SS101
 Type : CPHS
 Pore Size : 0.2 µm (0.45 µm + 0.2 µm)
 Lot Number : CS8460C SI.No. 005

SPECIFICATION

Length	10"
Filter Media	Polyethersulfone Membrane
Drainage Layers	Polyester
Plastic Components	Polypropylene
Differential Pressure	< 3.5 Kg/cm ² at 25°C
Maximum operating Temperature	80 °C at < 2 Kg/cm ²
Reverse Pressure	< 0.7 Kg/cm ² at 25°C
Sterilization	By Autoclaving or Steam-in-place (SIP)

LOT RELEASE CRITERIA

- 100% Integrity Tested** : The cartridge filter has been tested for integrity by Air Diffusion Flow test and Bubble Point test using DI water.
 Diffusion flows with DI water were: ≤ 30 ml/min @ 2.60 kg/cm²
 Bubble point value with DI water was: ≥ 50 psi (3.44 Bar)
 The cartridge filter is also certified for integrity by Bubble point test using 50% IPA/Water solution.
 Bubble point with 50% IPA/Water solution is ≥ 16 psi (1.10 Bar)
- Water Flow Rate** : ≥ 30 lpm @ 0.70 Kg/cm² @ 27 °C
- Microbial Challenge Test** : Retains ≥ 10⁷ organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838-05 methodology.
- VALIDATED FOR**
- Heat Stability** : Maintains integrity after 25 Steam sterilization cycles at 135 °C for 30 minutes each.
- Bacterial Endotoxin** : Aqueous extracts exhibit < 0.25 EU/mL as established by Limulus Amebocyte Lysate (LAL) test as per USP <85>.
- Extractable** : Within limits as specified in USP.
- Oxidizable matter** : Passes test as per USP.
- Biosafety** : Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.
- Cytotoxicity** : Passes Biological Reactivity Tests, *In Vitro* as described in USP <87>.
- Indirect Food Additives** : Passes as per FDA 21CFR 177.1520(a)1(i).
- Particle Release** : Passes test as per USP <788>, "Particulate matter in Injections".
- Fiber Release** : Complies with FDA 21CFR 210.3(b)(6).

CUSTOMER SUPPORT

mdi offers its unique interdisciplinary skills to provide solutions to specific problems. Please contact our factory or the local application specialist.



Head of Quality Assurance

Issue Date: 05-Mar-2020

Advanced Microdevices Pvt. Ltd.

21, Industrial Area, Ambala Cantt, INDIA,
 Tel: +91-171-2699290/ 2699274
 Website: www.mdimembrane.com
 Email: info@mdimembrane.com

An ISO 9001 Company