

# Certificate of Quality

The Hydrophilic PVDF Membrane Capsule filters have been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using **validated production processes**.

## **AseptiCap WS- $\gamma$ Hydrophilic PVDF Membrane Capsule Filters**

Catalog No. : DWS15336AARX101  
 Type : DWS  
 Pore Size : 0.1  $\mu$ m (0.2  $\mu$ m + 0.1  $\mu$ m)  
 Lot Number : DV9694E SI.No. 096  
 Manufacturing Date : 2024 - 05  
 Expiry Date : 2029 - 05

### SPECIFICATION

<b>Length</b>	5"
<b>Filter Media</b>	Hydrophilic PVDF Membrane
<b>Drainage Layers</b>	Polyester
<b>Housing</b>	Polypropylene
<b>Differential Pressure</b>	< 4Kg/cm <sup>2</sup> at 30 °C
<b>Maximum Operating Temperature</b>	80 °C @ < 2 Kg/cm <sup>2</sup>
<b>Sterilization</b>	Can be sterilized by Gamma Irradiation upto 50 kGy

### LOT RELEASE CRITERIA

#### 100% Integrity Tested

: The capsule filter has been tested for integrity by Air Diffusion Flow Test and Bubble Point Test using purified water.

Diffusion flows were:  $\leq$  8.0 ml/min @ 3.52 kg/cm<sup>2</sup>

Bubble point was:  $\geq$  70 psi (4.83 Bar).

#### Typical Water Flow Rate

: 700 ml/min @ 0.14 Kg/cm<sup>2</sup> @ 27 °C

#### Microbial Challenge Test

: Retains  $\geq$  10<sup>7</sup> organisms/cm<sup>2</sup> of *Acholeplasma laidlawii* (ATCC 23206).

### VALIDATED FOR

#### Bubble point (50% IPA)

: The filter is certified/validated for integrity by Bubble point test using 50% IPA/Water solution. Bubble point  $\geq$  28 psi (1.93 Bar)

#### Bacterial Endotoxin

: Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) test as per USP <85>.

#### Extractable with WFI

: Passes NVR test as per USP <661>.

#### Oxidizable substances

: Passes test as per USP<1231>.

#### 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).

#### Total Organic Carbon

: Meets USP <643> limit of 500 ppb for total organic carbon after flushing specified volume of water for injection.

#### Conductivity

: Meets USP <645> limit of 1.3  $\mu$ S/cm at 25 °C for water conductivity after flushing specified volume of water for injection.

### CUSTOMER SUPPORT

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

T. No.: COQ/CAP/013-04



Head of Quality Assurance

Issue Date: 01-May-24

### Advanced Microdevices Pvt. Ltd.

Jawahargarh Road,  
 Village-Tepla, Ambala, INDIA.  
 Tel: +91-171-2699290/2699274  
 Website: www.mdimembrane.com  
 Email: info@mdimembrane.com

**An ISO 9001 Company**