mdi
Membrane Technologies

Certificate of Quality

The Capsule filter has been manufactured in a **mdi** facility in compliance with **ISO 9001** regulations using ***validated production processes***.

AseptiCap VK-γ Capsule Filter

Catalog No.	: DVKX5301DDRX101	
Type	: DVK	
Pore Size	: 0.2 µm	
Lot Number	: DK8974L	Sl.No. 423
Manufacturing Date	: 2024 - 12	
Expiry Date	: 2029 - 12	

SPECIFICATION

Length	5”
Filter Media	Hydrophilic Polyethersulfone (PES)
	Hydrophobic PVDF
Drainage Layers	Polyester
Housing	Polypropylene
Differential Pressure	< 4Kg/cm² (60 psi) at 30 °C
Maximum operating Temperature	80 °C @ < 2 Kg/cm² (30 psi)
Sterilization	Can be sterilized by Gamma Irradiation upto 50 kGy

LOT RELEASE CRITERIA

100% Integrity Tested : The capsule filter has been tested for integrity by Bubble point test using 50% IPA/Water solution. Bubble point was: ≥ 18 psi (1.24 Bar)

Typical Water Flow Rate : 7.5 lpm @ 0.70 Kg/cm² @ 27 °C

Microbial Challenge Test : Retains ≥ 10^7 organisms/cm² of *B. diminuta* ATCC 19146 challenge as per ASTM F838 methodology.

VALIDATED FOR

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

Oxidizable matter : Passes test as per USP.

Biosafety : Passes Biological Reactivity Tests, *In Vivo* for Class VI plastic as described in USP <88>.

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).

Conductivity : Meets USP <645> limit of 1.3 µS/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/027-00

Head of Quality Assurance

Issue Date: 17-Dec-24

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An ISO 9001 Company