mdi
Membrane Technologies

Certificate of Quality

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

ClariPro GK-γ Membrane Prefilter Capsule

Catalog No.	: DGKX5304DDXX301
Type	: DGK-S
Pore Size	: 0.5 µm (Nominal)
Lot Number	: DK9897G Sl.No. 012
Ster. No.	: R012
Expiry Date	: 2019 - 07

SPECIFICATION

Length	5”
Filter Media	Polyethersulfone Membrane with Microglassfiber Prefilter
Drainage Layers	Polyester
Housing	Polypropylene
Differential Pressure	< 4Kg/cm² at 30 °C
Maximum Operating Temperature	80 °C @ < 2Kg/cm²
Sterilization	Pre sterilized by Gamma Irradiation

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: ≥ 5 psi (0.33 Bar)

Water Flow Rate : ≥ 8.5 lpm @ 0.70 Kg/cm² @ 27 °C

Sterility : Samples passed the sterility test in accordance with U.S. pharmacopoeia.

VALIDATED FOR

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>.

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

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An ISO 9001 Company