Microfilm ™ Membrane Filter

CERTIFICATE OF QUALITY

0.45 um MCE Membrane Filter

Part Number: MFMCE047045GWS
Lot Number: 342078060
Expiry Date: 2029.07.06

ISO 9001 Quality Standard

The product was manufactured under Membrane Solutions Quality Management System and is approved by an accredited registering body to the ISO 9001 Quality Systems Standard.

Good Manufacturing Practices

This product was manufactured in a Membrane Solutions Facility which adheres to FDA Device Good Manufacturing Practice standards.

Non-Fiber Releasing

This product was manufactured with a MCE membrane which meets the criteria for a “non-fiber releasing ” filter as defined in 21 CFR 210.3(b)(6).

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Criteria

This manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications.

The Description of Membrane Filter

The MCE Membrane Filters are 47 mm in diameter, White and grid.

Lot Analysis

Each lot is tested against the following criteria:

Membrane Filter Analysis

Criteria	Specifications	Results
Maximum pore size of the membrane	0.45 µm as verified by bubble point and retention 10^7 organisms/cm² *Serratia marcescens ATCC® 14756 challenge.*	Conform
Mean membrane thickness	115±25µm	Conform
Bubble point	32±6 psi	Conform
Water flow Rate of the membrane	62.5±22.5 ml/min/cm² 100ml deionised water at 10psi vacuum at 25°C	Conform

Sterility Test

The sterilization method is irradiation sterilization. No growth was observed when sterilized samples were subjected to the seven day sterility test as described by USP.

Recovery

The membrane filter has been manufactured for use in enumeration of microorganisms by culture methods which compliance with ISO7704:2023.

Micro-organism	Specifications	Results
Staphylococcus aureus ATCC® 6538	Good growth after 24h at 30-35°C	Conform
Pseudomonas aeruginosa ATCC® 9027	Good growth after 24h at 30-35°C	Conform
Escherichia coli ATCC® 8739	Good growth after 24h at 30-35°C	Conform
Candida albicans ATCC® 10231	Good growth after 24h at 30-35°C	Conform

Tested By: _____ 07-09-2026

QC Technician