

Change Notice No.	Notification date	Implementation date
CN/F/24/004	April 27, 2024	May 04, 2024

Subject : Changes in integrity test specifications of mdi 0.1µm rated PES membrane filters w.r.t.:

- Re-definition of minimum 50% IPA/Water solution wetted bubble point specifications
- Reference wetting agent for lot release bubble point test

Scope : This change will affect the 0.1µm rated PES membrane filters having following catalog numbers: (# can be any alphabet or numeral):

- | | |
|-----------------|-----------------|
| ● CH2###36##### | ● IK###36##### |
| ● CHR###36##### | ● LK###36##### |
| ● CPH###36##### | ● MDKL##36##### |
| ● CPK###36##### | ● PLXX##36##### |
| ● CPM###36##### | ● SYKG##36##### |
| ● DK###36##### | ● SYPL##36##### |
| ● DP###36##### | ● VK###36##### |

Background:

This advance change notification is initiated to provide the user updated information regarding the 0.1µm rated PES membrane filters. The following changes (w.r.t. integrity testing) shall be made in product related literature such as Certificate of quality (CoQ), validation guide, user guide, datasheet etc. of mdi 0.1 µm rated PES membrane filters with catalog numbers as mentioned in the scope:

1. Re-definition of 50% IPA/Water solution wetted minimum bubble point specifications from existing 31psi (2138 mbar) to 26psi (1793 mbar)
2. Change of reference wetting agent for lot release bubble point test from existing 50% IPA/Water solution to water

The changes will have no impact whatsoever on the product performance or it's regulatory compliance.

Need for Change:

1. mdi 0.1µm rated PES membrane filters having catalog numbers as mentioned in the scope are tested for integrity by subjecting the 50% IPA/Water solution wetted filters to bubble point test against the minimum acceptable bubble point of 31psi (2138 mbar).

The retention characteristics of 0.1µm rated PES membrane filters with *Acholeplasma laidlawii* (ATCC 23206) have been re-validated and based on the re-validation studies, it has been decided to re-define the minimum 50% IPA/Water solution wetted bubble point from exiting 31psi (2138 mbar) to 26psi (1793 mbar) with a safety margin.

2. The lot release integrity testing of mdi 0.1µm rated PES membrane filters having catalog numbers as mentioned in the scope is performed by subjecting the 50% IPA/Water solution wetted filter to bubble point test in addition to water wetted air diffusion flow test (where applicable).

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In most of the pharmaceutical industries, use of 50% IPA/Water solution is not recommended or not practical for integrity testing the filter. Hence, it is necessary to establish the bubble point testing of filter with water as a wetting agent. So, it has been decided to test **mdi** 0.1µm rated PES membrane filters for water wetted bubble point against the minimum established bubble point of 65psi (4482 mbar).

However, the 50% IPA/Water solution (low surface tension reference wetting fluid) wetted bubble point test specifications will still be reflected as validation activity as suggested by the PDA Technical report No. 26, Revised 2008 on Sterilizing Filtration of Liquids, for preliminary trouble shooting in case of integrity failure with purified water.

No changes have been made to the materials of construction or manufacturing process or critical dimensions or traceability.

How Does It Affect the User:

From a practical point of view these changes will only re-define the integrity (bubble point) test specifications of **mdi** 0.1µm rated PES membrane filters having catalog number as mentioned in the scope. All product specifications including materials of construction as well as performance specifications (except bubble point test) shall remain unchanged. The said changes will be reflected in the accompanying product literatures such as CoQ, validation guide, user guide, datasheet etc.

Implementation of Change:

mdi 0.1µm rated PES membrane filters with catalog numbers as mentioned in the scope, released after the implementation date will be with product literature having updated information regarding integrity test specifications.

However, the available stock of **mdi** 0.1µm rated PES membrane filters with catalog number as mentioned in the scope and having existing product literature (without updated information on integrity test specifications) will be supplied til the stocks last. These filters can still be tested/comply the integrity test specifications given in the current Certificate of Quality.

In case you have any queries, please feel free to contact our Technical Support Team at 'info@mdimembrane.com'.



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