

CDER Standards Information Sheet

Recognition Category: Revision Reaffirmation New recognition

CDER Recognition Number: 2025-006

Standards Developing Organization (SDO) Name: ANSI/PDA

Standard Number: Standard 05-2021

Title of Standard: Consensus Method for Rating Filters for Mycoplasma Reduction

Scope/Abstract:

Description from the ANSI Webstore:

This test method establishes a standardized method for filter manufacturer rating of nominal 0.1 m-rated filter membrane for retention of mycoplasma using 47 mm discs and using *A. laidlawii* as the test organism. This method may also be used to evaluate mycoplasma retention of any filter intended for that use to determine the degree of removal that filter provides. It is also necessary for the filter manufacturer to validate filter devices that may require testing a wide variety of device sizes and configurations. Validation of the actual filter device is not addressed in this standard test method. Any appropriate end-user validation and/or qualification of 0.1 m-rated filter devices incorporating such membrane is also outside of the scope of this standard. This test is intended to be used by the filter manufacturer to validate a mycoplasma-retentive filter within a manufacturing process and to qualify a filter for a mycoplasma retention claim. Validation of a drug manufacturing process employing such a filter must be done under applicable process-specific conditions.

Extent of Recognition:

Complete Recognition

Rationale for Complete Recognition:

This standard is relevant to products regulated by CDER and is recognized based on its scientific and technical merit and/or because it supports existing regulatory policies.

Relevant Regulations, Guidance and/or Supporting Publications:

CDER Standards Recognition Program Mailbox:
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