



Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration¹

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NOTE—Fig. 1 was editorially updated and the year date changed on Sept. 30, 2015.

1. Scope

1.1 This test method determines the bacterial retention characteristics of membrane filters for liquid filtration using *Brevundimonas diminuta* as the challenge organism. This test method may be employed to evaluate any membrane filter system used for liquid sterilization.

1.2 This test method is not intended to be used in performance of product- and process-specific validation of the bacterial retention characteristics of membrane filters to be used in pharmaceutical or biopharmaceutical sterilizing filtration, or both. Process- and product-specific bacterial retention validation should be carried out using the intended product manufacturing process parameters and the product solution or surrogate as the carrier fluid.

1.3 The values stated in SI units are to be regarded as standard.

1.3.1 *Exception*—The inch-pound values given for units of pressure are to be regarded as standard; SI unit conversions are shown in parentheses.

1.4 *This standard may involve hazardous materials, operations, and equipment. This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

D1193 Specification for Reagent Water

¹ This test method is under the jurisdiction of ASTM Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products and is the direct responsibility of Subcommittee E55.03 on General Pharmaceutical Standards.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

3. Terminology

3.1 Definitions:

3.1.1 *log reduction value*—the logarithm to the base 10 of the ratio of the number of microorganisms in the challenge to the number of organisms in the filtrate.

4. Summary of Test Method

4.1 After sterilization, the test filter is challenged with a suspension of *B. diminuta* (ATCC 19146³) at a concentration of 10⁷ organisms per cm² of effective filtration area (EFA) at a maximum differential pressure across the test filter of 30 psig (206 kPa) and a flow rate of 2 to 4 × 10⁻³ LPM per cm² of effective filtration area. The entire filtrate is then filtered through an analytical membrane filter disc, which is subsequently incubated on a solidified growth medium. Microorganisms that are not retained by the filter being tested will develop into visible colonies on the analysis membrane and can then be enumerated.

5. Significance and Use

5.1 This test method is designed to assess the retentivity of a sterilizing filter under standard challenge conditions.

5.1.1 A challenge of 10⁷ bacteria per cm² of effective filtration area is selected to provide a high degree of assurance that the filter will be challenged uniformly across the membrane surface to assure it will quantitatively retain large numbers of organisms. The model challenge organism, *B. diminuta*, is widely considered to be a small bacterium and is recognized as an industry standard for qualifying sterilizing filters. Other species may represent a worst-case test in terms of ability to penetrate a filter. This test does not provide assurance that filters can completely retain such bacteria.

5.1.2 The analytical procedure utilized in this test method provides a method to assign a numerical value to the filtration efficiency of the filter being evaluated under standard filtration conditions. For the purpose of product sterility assurance, additional process-specific studies should be performed.

³ Available from American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, VA 20110, <http://www.atcc.org>.