



Standard Guide for Biomedical Grade Water ¹

This standard is issued under the fixed designation D 5196; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide is intended to describe the physical and chemical characteristics of water to be used whenever critical purity is essential to the use intended in clinical, pharmaceutical, biophysical, biomedical, chemical, physical research applications, or a combination of these. This guide is not intended for use in preparing water for injectables. Generally, the appropriate use of this guide may include experiments involving tissue culture, chromatography, mass spectroscopy, or analysis where molecular quantities of impurities may be important.

1.2 *This standard does not purport to address all of the safety problems, 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:

- D 1125 Test Methods for Electrical Conductivity and Resistivity of Water ²
- D 1129 Terminology Relating to Water ²
- D 1426 Test Methods for Ammonia Nitrogen in Water ²
- D 1428 Test Methods for Sodium and Potassium in Water and Water-Formed Deposits by Flame Photometry ³
- D 3919 Practice for Measuring Trace Elements in Water by Graphite Furnace Atomic Absorption Spectrophotometry ²
- D 3973 Test Method for Low Molecular Weight Halogenated Hydrocarbons in Water ⁴
- D 4453 Practice for Handling of Ultra-Pure Water Samples ²
- D 4517 Test Method for Low-Level Total Silica in High Purity Water by Flameless Atomic Absorption Spectroscopy ⁴
- D 4779 Test Method for Total, Organic, and Inorganic Carbon in High Purity Water by Ultraviolet (UV), or Persulfate Oxidation, or Both, and Infrared Detection ⁴

F 1094 Test Methods for Microbiological Monitoring of Water Used for Processing Electron and Microelectronic Devices by Direct-Pressure Tap Sampling Valve and by the Pre-Sterilized Plastic Bag Method ⁵

3. Terminology

3.1 *Definitions*—For definitions of terms used in this guide, refer to Terminology D 1129.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *endotoxins*—substances or by-products usually produced by gram negative micro-organisms which give a positive test for endotoxin in accordance with 8.24.

3.2.2 *heterotropic bacterial counts/1000 mL*—total number of viable micro-organisms present in the 1000-mL sample, excluding anaerobic and microaerophilic bacteria.

3.2.3 *total organic carbon*—carbon measured after inorganic carbon response has been eliminated by one of the prescribed ASTM methods.

3.2.4 *water*—water prepared in accordance with this guide.

4. Significance and Use

4.1 The purity of water is only relative and is usually defined by the limits of impurities found in the water as well as by the methods used to prepare and handle the water. Appendix X1 describes a method of preparation of moderate volumes of water with the highest purity practical using available equipment and techniques.

4.2 The method of preparation of water described in Appendix X1 is designed to remove organic, inorganic, volatile, particulate, and biological impurities to provide water that should meet the concentration limits in Table 1. These are suggested limits, since the actual maxima of the individual impurities will depend upon the required end use of the water. The limits in the guide in most cases are dictated not by the desired maximum concentration of the impurities, but by the methods of analysis. More restrictive limits may be required by mutual consent of the parties concerned, provided a suitable test method is agreed upon.

4.3 The guide for the storage of high purity water is very important because impurities are added to the water in proportion to the solubility, area of contact, and time of contact between the water and the materials of containment. It is

¹ This guide is under the jurisdiction of ASTM Committee D-19 on Water and is the direct responsibility of Subcommittee D19.02 on General Specifications, Technical Resources, and Statistical Methods.

Current edition approved Oct. 15, 1991. Published February 1992.

² *Annual Book of ASTM Standards*, Vol 11.01.

³ *Discontinued 1990*—See 1989 *Annual Book of ASTM Standards*, Vol 11.01.

⁴ *Annual Book of ASTM Standards*, Vol 11.02.

⁵ *Annual Book of ASTM Standards*, Vol 10.04.