



Standard Practice for Conducting Equivalence Testing in Laboratory Applications¹

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1. Scope

1.1 This practice provides statistical methodology for conducting equivalence testing on numerical data from two sources to determine if their true means or variances differ by no more than predetermined limits.

1.2 Applications include (1) equivalence testing for bias against an accepted reference value, (2) determining means equivalence of two test methods, test apparatus, instruments, reagent sources, or operators within a laboratory or equivalence of two laboratories in a method transfer, and (3) determining non-inferiority of a modified test procedure versus a current test procedure with respect to a performance characteristic.

1.3 The guidance in this standard applies only to experiments conducted on a single material at a given level of the test result.

1.4 Guidance is given for determining the amount of data required for an equivalence trial. The control of risks associated with the equivalence decision is discussed.

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *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

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E456 Terminology Relating to Quality and Statistics
E2282 Guide for Defining the Test Result of a Test Method
E2586 Practice for Calculating and Using Basic Statistics

2.2 USP Standard:³

USP <1223> Validation of Alternative Microbiological Methods

3. Terminology

3.1 *Definitions*—See Terminology E456 for a more extensive listing of statistical terms.

3.1.1 *accepted reference value, n*—a value that serves as an agreed-upon reference for comparison, and which is derived as: (1) a theoretical or established value, based on scientific principles, (2) an assigned or certified value, based on experimental work of some national or international organization, or (3) a consensus or certified value, based on collaborative experimental work under the auspices of a scientific or engineering group. **E177**

3.1.2 *bias, n*—the difference between the expectation of the test results and an accepted reference value. **E177**

3.1.3 *confidence interval, n*—an interval estimate [L, U] with the statistics L and U as limits for the parameter θ and with confidence level $1 - \alpha$, where $\Pr(L \leq \theta \leq U) \geq 1 - \alpha$. **E2586**

3.1.3.1 *Discussion*—The confidence level, $1 - \alpha$, reflects the proportion of cases that the confidence interval [L, U] would contain or cover the true parameter value in a series of repeated random samples under identical conditions. Once L and U are given values, the resulting confidence interval either does or does not contain it. In this sense “confidence” applies not to the particular interval but only to the long run proportion of cases when repeating the procedure many times.

3.1.4 *confidence level, n*—the value, $1 - \alpha$, of the probability associated with a confidence interval, often expressed as a percentage. **E2586**

3.1.4.1 *Discussion*— α is generally a small number. Confidence level is often 95 % or 99 %.

3.1.5 *confidence limit, n*—each of the limits, L and U, of a confidence interval, or the limit of a one-sided confidence interval. **E2586**

¹ This test method is under the jurisdiction of ASTM Committee E11 on Quality and Statistics and is the direct responsibility of Subcommittee E11.20 on Test Method Evaluation and Quality Control.

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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 Available from U.S. Pharmacopeial Convention (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, <http://www.usp.org>.