



Standard Practice for Demonstrating Capability to Comply with the Test for Uniformity of Dosage Units¹

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^{ε1} NOTE—Editorial corrections made throughout in February 2013.

^{ε2} NOTE—Editorial corrections made throughout in December 2013.

1. Scope

1.1 This practice provides a general procedure for evaluating the capability to comply with the Uniformity of Dosage Units (UDU) test. This test is given in General Chapter <905> Uniformity of Dosage Units of the USP, in 2.9.40 Uniformity of Dosage Units of the Ph. Eur., and in 6.02 Uniformity of Dosage Units of the JP, and these versions are virtually interchangeable. For this multiple-stage test, the procedure computes a lower bound on the probability of passing the UDU test, based on statistical estimates made at a prescribed confidence level from a sample of dosage units.

1.2 This methodology can be used to generate an acceptance limit table, which defines a set of sample means and standard deviations that assures passing the UDU test for a prescribed lower probability bound, confidence level, and sample size.

1.3 *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

E2363 Terminology Relating to Process Analytical Technology in the Pharmaceutical Industry

E2709 Practice for Demonstrating Capability to Comply with an Acceptance Procedure

2.2 Other Documents:

JP Japanese Pharmacopoeia³

Ph. Eur. European Pharmacopoeia⁴

USP United States Pharmacopoeia⁵

3. Terminology

3.1 *Definitions*—See Terminology **E2363** for a more extensive listing of terms in ASTM Committee E55 standards.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *acceptable parameter region, n*—the set of values of parameters characterizing the distribution of test results for which the probability of passing the lot acceptance procedure is greater than a prescribed lower bound.

3.2.2 *acceptance limit, n*—the boundary of the acceptance region, for example, the maximum sample standard deviation for a given sample mean.

3.2.2.1 *Discussion*—The coefficient of variation (relative standard deviation) may be substituted for the standard deviation where applicable.

3.2.3 *acceptance region, n*—the set of values of parameter estimates (that is, sample mean and standard deviation) where confidence limits attain a prescribed lower bound on the probability of passing a lot acceptance procedure.

3.2.4 *confidence level, C, n*—the prescribed overall level for calculating the uncertainty region of the parameters from the sample estimates.

3.2.4.1 *Discussion*—The preset confidence level is stated as a percentage, for example, $100(1 - \alpha) = 95\%$, where α is a risk that is allocated to the two parameters being estimated.

¹ This practice 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 Available from the Pharmaceuticals and Medical Devices Agency, Japan, <http://jpd.b.nihs.go.jp>.

⁴ Available from the European Council, Strasbourg, France, <http://www.edqm.eu>.

⁵ Available from U.S. Pharmacopoeia (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, <http://www.usp.org>.