This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.



Designation: E2810 - 19

# Standard Practice for Demonstrating Capability to Comply with the Test for Uniformity of Dosage Units<sup>1</sup>

This standard is issued under the fixed designation E2810; 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  $(\varepsilon)$  indicates an editorial change since the last revision or reapproval.

# 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.
- 1.4 This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

# 2. Referenced Documents

2.1 ASTM Standards:<sup>2</sup>

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 Pharmacopoeia<sup>3</sup>

Ph. Eur. European Pharmacopoeia <sup>4</sup>

USP United States Pharmacopeia<sup>5</sup>

# 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 or minimum and maximum sample mean for given standard deviations.
- 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  $\alpha$  is a risk that is allocated to the two parameters being estimated.

<sup>&</sup>lt;sup>1</sup> 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.

Current edition approved April 1, 2019. Published August 2019. Originally approved in 2011. Last previous edition approved in 2017 as E2810 - 11 (2017). DOI: 10.1520/E2810-19.

<sup>&</sup>lt;sup>2</sup> 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.

<sup>&</sup>lt;sup>3</sup> Available from the Pharmaceuticals and Medical Devices Agency (PMDA), Shin-Kasumigaseki Building, 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013, Japan, https://www.pmda.go.jp.

<sup>&</sup>lt;sup>4</sup> Available from the European Directorate for the Quality of Medicines and Health Care (EDQM), Council of Europe, 7 allée Kastner, CS 30026, F-67081 Strasbourg, France, http://www.edqm.eu.

<sup>&</sup>lt;sup>5</sup> Available from U.S. Pharmacopeial Convention (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.



- 3.2.5 *lower probability bound, LB, n*—the nominal probability of passing the UDU test for a given set of parameter estimates.
- 3.2.6 multiple-stage acceptance procedure, n—a procedure that involves more than one stage of sampling and testing a given quality characteristic with one or more acceptance criteria per stage.
- 3.2.7 representative sample, n—a sample that consists of a number of units that are drawn based on rational criteria such as random, stratified, or systematic sampling and intended to assure that the sample accurately portrays the material being sampled.
- 3.2.8 *sampling plan, n*—scheme for selecting dosage units from locations within a batch for testing purposes.
- 3.2.8.1 *Discussion*—In this standard, either a single dosage unit is selected from each batch location (called Sampling Plan 1) or an equal but greater than one dosage unit is selected from each batch location (called Sampling Plan 2).
- 3.2.9 *uniformity of dosage units, UDU, n*—the degree of uniformity in the amount of the drug substance among dosage units
- 3.2.9.1 *Discussion*—The requirements of the UDU test apply to each drug substance in dosage units containing one or more drug substances, unless otherwise specified. The uniformity improves as the variability decreases.

### 4. Significance and Use

- 4.1 The methodology was originally developed (1-4)<sup>6</sup> for use in drug content uniformity and dissolution but has general application to any multistage test with multiple acceptance criteria. Practice E2709 summarizes the statistical aspects of this methodology. This practice applies the general methodology of Practice E2709 specifically to the UDU test.
- 4.1.1 While other methods can be used to estimate the probability of passing the UDU test, they are outside the scope of this practice.
- 4.2 The UDU test procedure describes a two-stage sampling test, where at each stage one can pass or continue testing, and the decision to fail is deferred until the second stage. At each stage there are acceptance criteria on the test results as outlined in Table 1.
- 4.3 The UDU test is a market standard. The USP General Notices include the following statement about compendial standards. "The similarity to statistical procedures may seem to suggest an intent to make inference to some larger group of units, but in all cases, statements about whether the compendial standard is met apply only to the units tested." Therefore, the

**TABLE 1 Uniformity of Dosage Units Test Procedure** 

Note 1—All measurements of dosage units and criteria values are in percentage label claim (%LC). At each stage calculate the sample average, X—, and the sample standard deviation, s.

Stage	Number Tested	Pass Stage If:
S <sub>1</sub>	10	$ M - \bar{X}  + 2.4 \text{ s} \le 15.0$ , where M is defined below.
S <sub>2</sub>	20	<ul> <li>(1)  M - X̄  + 2.0 s ≤ 15.0, using all 30 results (S₁ + S₂).</li> <li>(2) No dosage unit is outside the maximum allowed range of 0.75 * M to 1.25 * M.</li> </ul>

M is defined as follows:

If T is less than or equal to 101.5 %LC, and (1) If  $\bar{X}$  is less than 98.5 %LC, then

(1) If X is less than 98.5 %LC, then M = 98.5 %LC. (2) If  $\overline{X}$  is between 98.5 and 101.5 %LC, then  $M = \overline{X}$ .

(3) If  $\bar{X}$  is greater than 101.5 %LC, then M = 101.5 %LC.

If T is greater than 101.5 %LC, and

(1) If  $\bar{X}$  is less than 98.5 %LC, then M = 98.5 %LC. (2) If  $\bar{X}$  is between 98.5 and T, then  $M = \bar{X}$ .

(3) If  $\bar{X}$  is greater than T, then M = T.

T is the target content per dosage unit at the time of manufacture, expressed as %LC. Unless otherwise specified in the individual monograph, T is 100.0 %LC.

<sup>&</sup>lt;sup>6</sup> The boldface numbers in parentheses refer to a list of references at the end of this standard.

UDU procedure is not intended for inspecting uniformity of finished product for lot/batch release or as a lot inspection procedure.

- 4.3.1 The UDU test defines a product requirement to be met at release and throughout the shelf-life of the product.
- 4.3.2 Passing the UDU test once does not provide statistical assurance that a batch of drug product meets specified statistical quality control criteria.
- 4.4 This practice provides a practical specification that may be applied when uniformity of dosage units is required. An acceptance region for the mean and standard deviation of a set of test results from the lot is defined such that, at a prescribed confidence level, the probability that a future sample from the lot will pass the UDU test is greater than or equal to a prespecified lower probability bound. Having test results fall in the acceptance region provides assurance that a sample would pass the UDU test with at least the specified lower bound probability. This procedure does not account for any decrease in potency during the shelf life, which could affect the ability to meet the UDU test requirements.
- 4.5 This practice can be used as an element for process demonstration or validation, continuous process verification, in-process testing, or lot release (acceptance). As the circumstances and available information vary in these different application areas, this practice does not prescribe a specific target, sample size, lower probability bound, or confidence level. These must be prospectively selected by the user and may be different from those used in the acceptance limit tables provided in this practice.

### 5. Procedure

- 5.1 Generating The Acceptance Limit Table:
- 5.1.1 The general procedure that generates the acceptance limit tables is described in Practice E2709 and the specific procedure for application to the UDU test is described in the

- literature (4). A simplified description on the construction and use of these tables is given in this section. A computer program is required to generate the tables given a target T as a percentage of label claim (LC), a lower probability bound LB, a confidence level C, and a sample size n.
- 5.1.2 The first step is to determine the acceptable parameter region. On a two-dimensional content space consisting of the true mean ( $\mu$ ) on the horizontal axis and standard deviation ( $\sigma$ ) on the vertical axis the upper 95 % LB boundary of this region is defined by a contour, a curve that is concave downward and depicted by the solid curve in Fig. 1. The simulated 95 % boundary for the actual probability of passing the USP UDU test is defined by the dashed contour that shows the effect of generating a lower bound. The LB contour is determined by the LB probability (95 %) and the target under the assumption that the dosage unit content is normally distributed. The acceptable parameter region is the set of points on or below the contour. Any ( $\mu$ ,  $\sigma$ ) pair in the acceptable region would pass the UDU test with a probability of at least the LB.
- 5.1.3 The second step is to generate the *acceptance limit curve* that defines the acceptance region.

### **SAMPLING PLAN 1**

- 5.1.4 As described in Practice E2709, the sample mean  $(\bar{X})$  and sample standard deviation (s) estimate the population parameters  $\mu$  and  $\sigma$  within C % confidence limits as chosen by the user. The joint confidence region for  $\mu$  and  $\sigma$  (5) has the shape of an inverted triangle around a  $(\bar{X}, s)$  pair as depicted in Fig. 2 with the lowest vertex at  $(\bar{X}, 0)$ .
- 5.1.4.1 To create an acceptance region, a value of  $\bar{X}$  is selected starting with s=0, then the confidence region is expanded by increasing s until one of the upper vertices just touches the *acceptable parameter region*. The size of the confidence region is determined by C and n. This value of s defines a point on the acceptance limit curve at  $(\bar{X}, s)$ . Additional selections of  $\bar{X}$  then generate the *acceptance limit*

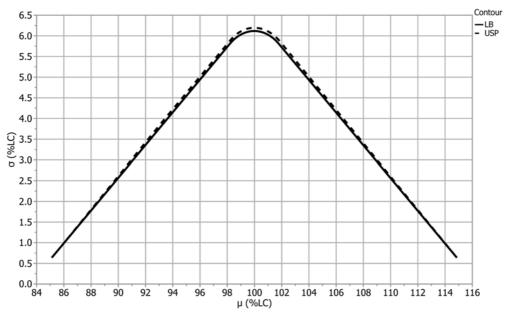
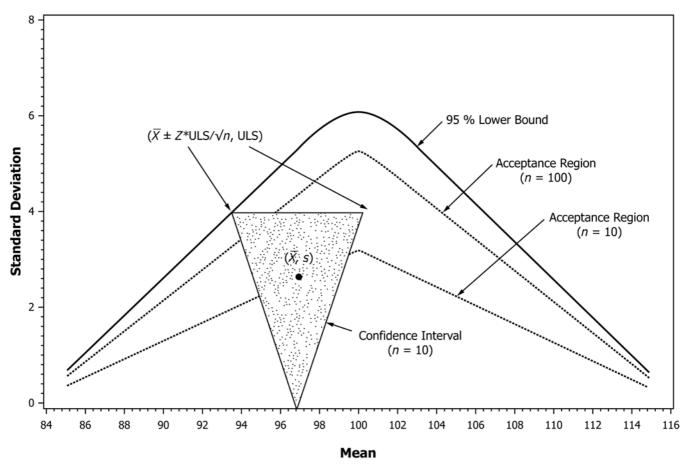


FIG. 1 Example of 95 % Lower Bound and Simulated Probabilities of Passing USP UDU <905>



Note 1—All points below the lower bound contour have higher than a 95 % chance of passing UDU test if mean and standard deviation are known. All points below the acceptance region contours pass the associated acceptance limit table for n = 100 and n = 10. ULS is the upper confidence limit for  $\sigma$ .

Z is a standard normal critical value.

FIG. 2 Example of Simultaneous Confidence Interval with 95 % Lower Bound and Acceptance Regions

curve, as depicted as dotted lines in Fig. 2. Acceptance limit curves are shown for n = 10 and n = 100, illustrating that the acceptance limits approach the acceptable parameter region with increasing sample size.

5.1.5 Computer programs have been developed for generating acceptance limit tables, but these may not be available to all practitioners. This practice contains four acceptance limit tables for many practical use situations.

5.1.6 Using the Acceptance Limit Tables in This Practice—Various acceptance limit tables are given in Tables 2-5. In each table acceptance limits on the standard deviation are given for means ranging 90–110 % of LC in increments of 0.2 %LC for sample sizes ranging from n = 10 to n = 500. In all tables, the target is set at T = 100 %LC, so the acceptance limits for standard deviations are symmetrical around 100 %LC. This target is also required for interchangeability across the ICH regions (6). At the confidence level of C = 95 % used often in the regulatory arena, three levels of the probability lower bound are provided: LB = 90 % (Table 2), LB = 95 % (Table 3) and LB = 99 % (Table 4). These provide 90 %, 95 %, and 99 % coverage, respectively, of the population of dosage units under consideration. The usual coverage is 95 %.

5.1.6.1 Table 5 is provided at C = 90 % and LB = 95 % for comparison with Table 3 to demonstrate the effect of a lower confidence level.

Note 1—Tables can also be generated for other choices for ranges of means, such as 85.1 to 114.9 %LC, or for other sample sizes.

5.1.7 A representative sample of n dosage units is taken from the batch and the active content is measured on each unit, taken as a random sample or as a systematic sample (selecting and testing one unit at equally spaced time intervals of manufacture across the batch). Other sampling plans are outside the scope of this practice.

5.1.8 The sample average  $(\bar{X})$  and sample standard deviation (s) are calculated. Enter the table row with the sample average and the table column with the sample size to find the acceptance limit on the standard deviation. If the sample standard deviation is at or below the acceptance limit then it can be asserted at the C% confidence level that the batch will have an LB% chance of passing the UDU test. Some interpolation may be required for sample sizes and sample means not listed in the table.



TABLE 2 Acceptance Limits on Sample Standard Deviation (%LC) for T = 100 %LC, C = 95 %, LB = 90 %LC

Sample Average					S	ample Size (	n)				
(%LC)	10	30	40	50	60	80	100	120	150	200	500
100.0	2.91	4.36	4.65	4.84	4.99	5.19	5.33	5.43	5.54	5.66	5.93
99.8 or 100.2	2.88	4.31	4.59	4.79	4.94	5.14	5.28	5.38	5.50	5.62	5.9
99.6 or 100.4	2.84	4.26	4.54	4.74	4.89	5.09	5.24	5.34	5.45	5.58	5.8
99.4 or 100.6	2.81	4.21	4.49	4.69	4.83	5.04	5.18	5.29	5.40	5.53	5.8
99.2 or 100.8	2.77	4.16	4.43	4.63	4.77	4.98	5.13	5.23	5.35	5.48	5.7
99.0 or 101.0	2.74	4.10	4.38	4.57	4.72	4.92	5.07	5.17	5.29	5.43	5.7
98.8 or 101.2	2.70	4.05	4.32	4.52	4.66	4.86	5.01	5.11	5.23	5.37	5.6
98.6 or 101.4	2.67	4.00	4.27	4.46	4.60	4.80	4.94	5.05	5.17	5.30	5.6
98.4 or 101.6	2.63	3.95	4.21	4.40	4.54	4.74	4.88	4.99	5.10	5.24	5.5
98.2 or 101.8	2.60	3.89	4.16	4.34	4.48	4.68	4.82	4.92	5.04	5.17	5.4
98.0 or 102.0	2.56	3.84	4.10	4.28	4.42	4.62	4.75	4.86	4.97	5.10	5.4
97.8 or 102.2	2.53	3.79	4.05	4.22	4.36	4.55	4.69	4.79	4.90	5.03	5.3
97.6 or 102.4	2.49	3.74	3.99	4.17	4.30	4.49	4.62	4.72	4.84	4.97	5.2
97.4 or 102.6	2.46	3.68	3.93	4.11	4.24	4.43	4.56	4.66	4.77	4.90	5.2
97.2 or 102.8	2.42	3.63	3.88	4.05	4.18	4.36	4.50	4.59	4.70	4.83	5.1
97.0 or 103.0	2.39	3.58	3.82	3.99	4.12	4.30	4.43	4.53	4.63	4.76	5.0
96.8 or 103.2	2.35	3.53	3.77	3.93	4.06	4.24	4.37	4.46	4.56	4.69	4.9
96.6 or 103.4	2.32	3.48	3.71	3.87	4.00	4.18	4.30	4.39	4.50	4.62	4.9
96.4 or 103.6	2.28	3.42	3.65	3.81	3.94	4.11	4.23	4.33	4.43	4.55	4.8
96.2 or 103.8	2.24	3.42	3.60	3.76	3.88	4.11	4.23	4.33	4.43	4.48	4.7
96.0 or 104.0	2.24	3.32	3.54	3.70	3.82	3.99	4.17	4.20	4.30	4.40 4.41	4.7
95.8 or 104.2	2.17	3.26	3.48	3.64	3.76	3.92	4.04	4.13	4.23	4.34	4.6
95.6 or 104.4	2.14	3.21	3.43	3.58	3.70	3.86	3.98	4.06	4.16	4.27	4.5
95.4 or 104.6	2.10	3.16	3.37	3.52	3.63	3.80	3.91	3.99	4.09	4.20	4.4
95.2 or 104.8	2.07	3.11	3.31	3.46	3.57	3.73	3.84	3.93	4.02	4.13	4.3
95.0 or 105.0	2.03	3.05	3.26	3.40	3.51	3.67	3.78	3.86	3.95	4.06	4.3
94.8 or 105.2	2.00	3.00	3.20	3.35	3.45	3.61	3.71	3.79	3.88	3.99	4.2
94.6 or 105.4	1.96	2.95	3.15	3.29	3.39	3.54	3.65	3.73	3.82	3.92	4.1
94.4 or 105.6	1.93	2.89	3.09	3.23	3.33	3.48	3.58	3.66	3.75	3.85	4.1
94.2 or 105.8	1.89	2.84	3.03	3.17	3.27	3.42	3.52	3.59	3.68	3.78	4.0
94.0 or 106.0	1.86	2.79	2.98	3.11	3.21	3.35	3.45	3.53	3.61	3.71	3.9
93.8 or 106.2	1.82	2.74	2.92	3.05	3.15	3.29	3.39	3.46	3.54	3.64	3.8
93.6 or 106.4	1.79	2.68	2.86	2.99	3.09	3.23	3.32	3.39	3.47	3.57	3.8
93.4 or 106.6	1.75	2.63	2.81	2.93	3.03	3.16	3.25	3.33	3.40	3.50	3.7
93.2 or 106.8	1.72	2.58	2.75	2.87	2.97	3.10	3.19	3.26	3.34	3.43	3.6
93.0 or 107.0	1.68	2.52	2.69	2.81	2.90	3.03	3.12	3.19	3.27	3.36	3.5
92.8 or 107.2	1.65	2.47	2.64	2.75	2.84	2.97	3.06	3.13	3.20	3.28	3.5
92.6 or 107.4	1.61	2.42	2.58	2.70	2.78	2.91	2.99	3.06	3.13	3.21	3.4
92.4 or 107.6	1.57	2.36	2.52	2.64	2.72	2.84	2.93	2.99	3.06	3.14	3.3
92.2 or 107.8	1.54	2.31	2.47	2.58	2.66	2.78	2.86	2.92	2.99	3.07	3.2
92.0 or 108.0	1.50	2.26	2.41	2.52	2.60	2.71	2.80	2.86	2.92	3.00	3.2
91.8 or 108.2	1.47	2.20	2.35	2.46	2.54	2.65	2.73	2.79	2.86	2.93	3.1
91.6 or 108.4	1.43	2.15	2.30	2.40	2.48	2.59	2.66	2.72	2.79	2.86	3.0
91.4 or 108.6	1.40	2.10	2.24	2.34	2.42	2.52	2.60	2.65	2.72	2.79	2.9
91.2 or 108.8	1.36	2.04	2.18	2.28	2.35	2.46	2.53	2.59	2.65	2.72	2.8
91.0 or 109.0	1.33	1.99	2.13	2.22	2.29	2.39	2.47	2.52	2.58	2.65	2.8
90.8 or 109.2	1.29	1.94	2.13	2.16	2.23	2.33	2.47	2.45	2.51	2.58	2.7
90.6 or 109.4	1.29	1.89	2.07	2.10	2.23	2.33	2.40	2.45	2.31	2.50	2.6
	1.20	1.83		2.10	2.17	2.20	2.33	2.39	2.44	2.44	2.5
90.4 or 109.6	1.19	1.83	1.96 1.90	1.98	2.11	2.20	2.27	2.32	2.37	2.44	
90.2 or 109.8 90.0 or 110.0	1.19	1.78	1.90	1.98	1.99	2.14	2.20	2.25	2.30	2.37	2.5 2.4

5.1.8.1 Example 1—A sample of n = 60 dosage units provided dosage content statistics of  $\bar{X} = 98.6$  %LC and s = 3.91 %LC. Since s was below the upper limit of 4.41 %LC (using Table 3), we can state with 95 % confidence there is at least a 95 % probability that a future sample taken from the batch will meet the UDU test.

5.1.8.2 Example 2—A sample of n = 70 dosage units provided dosage content statistics of  $\bar{X} = 97.8$  %LC and s = 4.29 %LC. Since n = was not provided in the Table 3, we must interpolate between entry n = 60 with the upper limit 4.18 %LC and entry n = 80 with the upper limit 4.36 %LC as follows:

acceptance limit = 
$$4.18 + [(4.36 - 4.18)(80 - 70)/(80 - 60)]$$
  
=  $4.18 + [(0.18)(10)/(20)] = 4.27 \% LC$ 

Since s = 4.29 %LC was above the upper limit of 4.27 %LC, we cannot state with 95 % confidence there is at least a 95 % probability that a future sample taken from the batch will meet the UDU test.

5.1.8.3 Example 3—A sample of n = 60 dosage units provided dosage content statistics of  $\bar{X} = 98.6$  %LC and s = 3.91 %LC at time of manufacture. At the end of shelf life the dosage units are predicted to have lost potency such that the effective  $\bar{X} = 96.2$  %LC. Since s = 3.91 %LC was above the



TABLE 3 Acceptance Limits on Sample Standard Deviation (%LC) for T = 100 %LC, C = 95 %, LB = 95 %LC

Sample Average						Sample Size	e (n)				
(%LC)	10	30	40	50	60	80	100	120	150	200	500
100.0	2.81	4.18	4.46	4.64	4.78	4.98	5.11	5.21	5.31	5.43	5.69
99.8 or 100.2	2.77	4.13	4.41	4.59	4.73	4.93	5.07	5.16	5.27	5.39	5.67
99.6 or 100.4	2.74	4.08	4.35	4.54	4.68	4.88	5.02	5.12	5.23	5.35	5.64
99.4 or 100.6	2.70	4.04	4.30	4.49	4.63	4.83	4.96	5.07	5.18	5.30	5.60
99.2 or 100.8	2.67	3.99	4.26	4.43	4.57	4.77	4.91	5.01	5.12	5.25	5.55
99.0 or 101.0	2.64	3.94	4.20	4.39	4.51	4.71	4.85	4.95	5.07	5.20	5.49
98.8 or 101.2	2.60	3.88	4.15	4.33	4.47	4.65	4.79	4.89	5.01	5.14	5.44
98.6 or 101.4	2.57	3.84	4.09	4.27	4.41	4.59	4.73	4.83	4.94	5.07	5.38
98.4 or 101.6	2.54	3.79	4.03	4.21	4.35	4.54	4.67	4.77	4.88	5.01	5.31
98.2 or 101.8	2.50	3.74	3.99	4.16	4.29	4.48	4.61	4.70	4.82	4.94	5.25
98.0 or 102.0	2.47	3.68	3.93	4.11	4.23	4.42	4.55	4.65	4.75	4.88	5.18
97.8 or 102.2	2.43	3.64	3.88	4.05	4.18	4.36	4.49	4.58	4.68	4.81	5.11
97.6 or 102.4	2.40	3.58	3.83	3.99	4.12	4.29	4.42	4.52	4.63	4.74	5.05
97.4 or 102.6	2.37	3.54	3.77	3.93	4.06	4.24	4.36	4.45	4.56	4.68	4.97
97.2 or 102.8	2.33	3.49	3.71	3.88	4.00	4.18	4.30	4.39	4.49	4.62	4.90
97.0 or 103.0	2.30	3.43	3.67	3.82	3.95	4.11	4.24	4.33	4.43	4.55	4.83
96.8 or 103.2	2.26	3.39	3.61	3.77	3.88	4.06	4.17	4.27	4.37	4.48	4.76
96.6 or 103.4	2.23	3.33	3.55	3.71	3.83	4.00	4.12	4.20	4.30	4.41	4.69
96.4 or 103.6	2.20	3.29	3.50	3.65	3.77	3.93	4.05	4.14	4.23	4.35	4.62
96.2 or 103.8	2.16	3.23	3.44	3.60	3.71	3.88	3.99	4.07	4.17	4.28	4.55
96.0 or 104.0	2.13	3.18	3.40	3.54	3.66	3.81	3.93	4.01	4.10	4.21	4.47
95.8 or 104.2	2.09	3.13	3.34	3.49	3.59	3.76	3.86	3.95	4.04	4.15	4.41
95.6 or 104.4	2.06	3.08	3.29	3.43	3.54	3.69	3.80	3.88	3.98	4.08	4.34
95.4 or 104.6	2.03	3.03	3.23	3.38	3.48	3.63	3.74	3.82	3.91	4.02	4.26
95.2 or 104.8	1.99	2.98	3.18	3.31	3.42	3.57	3.67	3.75	3.85	3.94	4.19
95.0 or 105.0	1.96	2.93	3.13	3.26	3.36	3.52	3.61	3.70	3.78	3.88	4.12
94.8 or 105.2	1.92	2.87	3.07	3.20	3.31	3.45	3.56	3.63	3.72	3.81	4.05
94.6 or 105.4	1.89	2.83	3.02	3.15	3.24	3.39	3.49	3.57	3.65	3.75	3.98
94.4 or 105.6	1.86	2.78	2.96	3.09	3.19	3.33	3.43	3.50	3.58	3.68	3.91
94.2 or 105.8	1.82	2.72	2.91	3.03	3.13	3.27	3.36	3.44	3.51	3.61	3.83
94.0 or 106.0	1.79	2.67	2.85	2.98	3.07	3.21	3.30	3.37	3.45	3.54	3.77
93.8 or 106.2	1.75	2.63	2.80	2.92	3.01	3.14	3.24	3.31	3.39	3.47	3.70
93.6 or 106.4	1.72	2.57	2.74	2.86	2.96	3.09	3.17	3.25	3.32	3.41	3.62
93.4 or 106.6	1.69	2.52	2.69	2.81	2.90	3.03	3.11	3.18	3.25	3.34	3.55
93.2 or 106.8	1.65	2.47	2.64	2.75	2.84	2.96	3.05	3.11	3.19	3.27	3.48
93.0 or 107.0	1.62	2.42	2.59	2.70	2.78	2.90	2.99	3.05	3.12	3.21	3.40
92.8 or 107.2	1.58	2.37	2.52	2.64	2.72	2.84	2.92	2.99	3.05	3.14	3.33
92.6 or 107.4	1.55	2.32	2.47	2.58	2.67	2.78	2.86	2.93	2.99	3.07	3.27
92.4 or 107.6	1.52	2.26	2.42	2.52	2.61	2.72	2.80	2.86	2.93	3.00	3.20
92.4 or 107.8	1.48	2.20	2.36	2.32	2.54	2.72	2.74	2.79	2.86	2.93	3.13
92.2 or 107.8	1.45	2.16	2.30	2.41	2.48	2.59	2.74	2.73	2.80	2.87	3.15
91.8 or 108.2	1.45	2.10	2.26	2.41	2.43	2.53	2.61	2.73	2.73	2.80	2.97
91.6 or 108.4	1.38	2.11	2.20	2.30	2.43	2.33	2.55	2.60	2.73	2.73	2.90
91.4 or 108.6	1.35	2.00	2.20	2.30	2.31	2.47	2.33	2.54	2.60	2.73	2.83
91.4 or 108.8	1.35	1.96	2.15	2.24	2.31	2.41	2.49	2.54 2.47	2.54	2.60	2.83
91.2 or 108.8 91.0 or 109.0	1.28	1.96	2.09	2.18	2.25	2.35	2.43	2.47	2.54 2.47	2.53	2.76
	1.28	1.91	1.98	2.13	2.19		2.36		2.47	2.53	2.69
90.8 or 109.2		1.86	1.98	2.07	2.13	2.23 2.17	2.30	2.34 2.28	2.40	2.46	2.62
90.6 or 109.4	1.21			1.95			2.23		2.34		
90.4 or 109.6	1.18	1.75	1.87		2.02	2.11		2.21		2.33	2.48
90.2 or 109.8	1.14	1.70	1.82	1.90	1.96	2.05	2.11	2.16	2.20	2.26	2.41
90.0 or 110.0	1.11	1.66	1.76	1.85	1.90	1.99	2.04	2.09	2.13	2.20	2.33

upper limit of 3.71 %LC (using Table 3), we cannot state with 95 % confidence there is at least a 95 % probability that a future sample taken from the batch will meet the UDU test throughout the shelf life.

# **SAMPLING PLAN 2**

5.1.9 As described in Practice E2709, Sampling Plan 2 (two-stage sampling) divides the population into primary sampling units (locations). L locations are selected and from each of them a subsample of r items is taken for a total of N = Lxr units. The variance of a single observation,  $\sigma^2$ , is the sum of between-location and within-location variances.  $\sigma$  is esti-

mated by  $\sqrt{((1/r)*\text{MSB}+(1-1/r)\text{MSE})}$  where MSB and MSE are the between location and within location mean square errors from the analysis of variance table. The confidence limit for  $\sigma^2$  is determined using MSE and MSB (see Practice E2709). The joint confidence region is as in Sampling Plan 1. For fixed values of the between and within location standard deviations, the sample mean  $(\bar{X})$  is set at 83.5. Then the confidence region is expanded by increasing the sample mean until the left vertex just touches the acceptable parameter region. Then the sample mean is set at 116.5 and the confidence region is expanded by decreasing the sample mean until the



TABLE 4 Acceptance Limits on Sample Standard Deviation (%LC) for T = 100 %LC, C = 95 %, LB = 99 %LC

Sample Average					5	Sample Size	(n)				
(%LC)	10	30	40	50	60	80	100	120	150	200	500
100.0	2.62	3.88	4.13	4.31	4.43	4.61	4.73	4.82	4.92	5.03	5.27
99.8 or 100.2	2.59	3.84	4.09	4.26	4.39	4.57	4.69	4.78	4.88	4.99	5.25
99.6 or 100.4	2.56	3.79	4.04	4.21	4.34	4.52	4.64	4.73	4.84	4.95	5.22
99.4 or 100.6	2.53	3.75	3.99	4.16	4.29	4.47	4.59	4.68	4.78	4.90	5.17
99.2 or 100.8	2.49	3.70	3.94	4.11	4.23	4.41	4.54	4.63	4.73	4.85	5.13
99.0 or 101.0	2.46	3.65	3.89	4.06	4.18	4.36	4.48	4.57	4.68	4.79	5.07
98.8 or 101.2	2.43	3.61	3.84	4.01	4.13	4.31	4.43	4.52	4.62	4.74	5.02
98.6 or 101.4	2.40	3.56	3.79	3.95	4.08	4.25	4.37	4.46	4.56	4.68	4.96
98.4 or 101.6	2.37	3.51	3.74	3.90	4.02	4.19	4.31	4.40	4.50	4.62	4.90
98.2 or 101.8	2.34	3.47	3.69	3.85	3.97	4.14	4.26	4.34	4.44	4.56	4.83
98.0 or 102.0	2.31	3.42	3.64	3.80	3.92	4.08	4.20	4.29	4.38	4.50	4.77
97.8 or 102.2	2.27	3.37	3.59	3.75	3.86	4.03	4.14	4.23	4.32	4.44	4.70
97.6 or 102.4	2.24	3.33	3.54	3.70	3.81	3.97	4.09	4.17	4.27	4.38	4.64
97.4 or 102.6	2.21	3.28	3.49	3.64	3.76	3.92	4.03	4.11	4.21	4.31	4.58
97.2 or 102.8	2.18	3.23	3.45	3.59	3.70	3.86	3.97	4.05	4.15	4.25	4.51
97.0 or 103.0	2.15	3.19	3.40	3.54	3.65	3.81	3.91	4.00	4.09	4.19	4.45
96.8 or 103.2	2.12	3.14	3.35	3.49	3.60	3.75	3.86	3.94	4.03	4.13	4.38
96.6 or 103.4	2.08	3.09	3.30	3.44	3.54	3.69	3.80	3.88	3.97	4.07	4.32
96.4 or 103.6	2.05	3.05	3.24	3.38	3.49	3.64	3.74	3.82	3.91	4.01	4.25
96.2 or 103.8	2.02	3.00	3.20	3.33	3.43	3.58	3.68	3.76	3.85	3.95	4.19
96.0 or 104.0	1.99	2.95	3.14	3.28	3.38	3.53	3.63	3.70	3.79	3.88	4.12
95.8 or 104.2	1.96	2.91	3.10	3.23	3.33	3.47	3.57	3.64	3.73	3.82	4.06
95.6 or 104.4	1.93	2.86	3.05	3.18	3.27	3.41	3.51	3.58	3.67	3.76	3.99
95.4 or 104.6	1.89	2.81	2.99	3.10	3.22	3.36	3.45	3.52	3.61	3.70	3.92
95.2 or 104.8	1.86	2.76	2.94	3.07	3.16	3.30	3.40	3.47	3.55	3.64	3.86
95.0 or 105.0	1.83	2.70	2.89	3.02	3.10	3.25	3.34	3.41	3.48	3.58	3.79
94.8 or 105.2	1.80	2.72	2.84	2.97	3.06	3.19	3.28	3.35	3.43	3.51	3.73
94.6 or 105.4	1.77	2.62	2.79	2.91	3.00	3.13	3.22	3.29	3.43	3.45	3.66
94.4 or 105.6	1.77	2.58	2.79	2.86	2.95	3.13	3.16	3.29	3.30	3.45	3.60
	1.73	2.58	2.74	2.80	2.95	3.08	3.16	3.23 3.17	3.30	3.39	
94.2 or 105.8				2.76							3.53
94.0 or 106.0	1.67	2.48	2.64		2.84	2.96	3.05	3.11	3.18	3.26	3.46
93.8 or 106.2	1.64	2.43	2.59	2.70	2.79	2.91	2.99	3.05	3.12	3.20	3.40
93.6 or 106.4	1.61	2.39	2.54	2.65	2.73	2.85	2.93	2.99	3.06	3.14	3.33
93.4 or 106.6	1.58	2.34	2.49	2.60	2.68	2.79	2.87	2.93	3.00	3.08	3.27
93.2 or 106.8	1.54	2.29	2.44	2.55	2.62	2.74	2.82	2.87	2.94	3.02	3.20
93.0 or 107.0	1.51	2.24	2.39	2.49	2.57	2.68	2.76	2.82	2.88	2.95	3.14
92.8 or 107.2	1.48	2.20	2.34	2.44	2.52	2.63	2.70	2.76	2.82	2.89	3.07
92.6 or 107.4	1.45	2.15	2.29	2.39	2.46	2.57	2.64	2.70	2.76	2.83	3.00
92.4 or 107.6	1.42	2.10	2.24	2.34	2.41	2.51	2.58	2.64	2.70	2.77	2.94
92.2 or 107.8	1.38	2.06	2.19	2.28	2.36	2.46	2.53	2.58	2.64	2.71	2.87
92.0 or 108.0	1.35	2.01	2.14	2.23	2.30	2.40	2.47	2.52	2.58	2.64	2.8
91.8 or 108.2	1.32	1.96	2.09	2.18	2.25	2.34	2.41	2.46	2.52	2.58	2.74
91.6 or 108.4	1.29	1.91	2.04	2.13	2.19	2.29	2.35	2.40	2.46	2.52	2.67
91.4 or 108.6	1.26	1.87	1.99	2.07	2.14	2.23	2.29	2.34	2.39	2.46	2.6
91.2 or 108.8	1.23	1.82	1.94	2.02	2.08	2.17	2.24	2.28	2.34	2.39	2.54
91.0 or 109.0	1.19	1.77	1.89	1.97	2.03	2.12	2.18	2.22	2.27	2.33	2.48
90.8 or 109.2	1.16	1.73	1.84	1.92	1.98	2.06	2.12	2.16	2.21	2.27	2.4
90.6 or 109.4	1.13	1.68	1.79	1.86	1.92	2.00	2.06	2.11	2.15	2.21	2.34
90.4 or 109.6	1.10	1.63	1.74	1.81	1.87	1.95	2.00	2.04	2.09	2.15	2.28
90.2 or 109.8	1.07	1.58	1.69	1.76	1.81	1.89	1.95	1.99	2.03	2.08	2.21
90.0 or 110.0	1.03	1.54	1.64	1.71	1.76	1.84	1.89	1.93	1.97	2.02	2.15

right vertex just touches the acceptable parameter region. The size of the confidence region is determined by C, L, and r.

5.1.10 Computer programs have been developed for generating acceptance limit tables, but these may not be available to all practitioners. The International Society for Pharmaceutical Engineering (ISPE) has made available information for common tables for Sampling Plans 1 and 2, a SAS program, and other useful tools.<sup>7</sup>

5.1.11 Using the Acceptance Limit Tables in This Practice—For a given sampling plan with L locations with r dosage units tested at each location and a specified confidence level and probability of passing the USP UDU test, the acceptance limit table provides a lower and upper range for the overall L  $\times$  r mean based on the pooled within location standard deviation (SE) and the standard deviation of the L location means (not the between location variance component). The pooled location standard deviation is the square root of the average L within location variances.

<sup>&</sup>lt;sup>7</sup> https://www.ispe.org/initiatives/blend-uniformity-content-uniformity/tools

TABLE 5 Acceptance Limits on Sample Standard Deviation (%LC) for T = 100 %LC, C = 90 %, LB = 95 %LC

			7 = 10	0 %LC, C							
Sample Average	-					ample Size	` '				
(%LC)	10	30	40	50	60	80	100	120	150	200	500
100.0	3.21	4.47	4.71	4.88	5.00	5.16	5.27	5.35	5.44	5.54	5.76
99.8 or 100.2	3.17	4.42	4.67	4.83	4.95	5.12	5.23	5.32	5.41	5.51	5.74
99.6 or 100.4	3.13	4.37	4.61	4.78	4.90	5.07	5.19	5.27	5.36	5.47	5.71
99.4 or 100.6	3.09	4.32	4.56	4.72	4.85	5.02	5.14	5.22	5.32	5.42	5.67
99.2 or 100.8	3.06	4.27	4.50	4.67	4.79	4.96	5.08	5.17	5.26	5.37	5.63
99.0 or 101.0	3.02	4.21	4.45	4.61	4.73	4.91	5.02	5.11	5.21	5.32	5.58
98.8 or 101.2	2.98	4.16	4.39	4.55	4.67	484	4.96	5.05	5.15	5.26	5.52
98.6 or 101.4	2.94	4.11	4.34	4.50	4.62	4.78	4.90	4.99	5.08	5.20	5.46
98.4 or 101.6	2.90	4.05	4.28	4.44	4.55	4.72	4.84	4.93	5.02	5.13	5.40
98.2 or 101.8	2.86	4.00	4.22	4.38	4.50	4.66	4.78	4.86	4.96	5.07	5.33
98.0 or 102.0	2.82	3.95	4.17	4.32	4.44	4.60	4.71	4.80	4.89	5.00	5.26
97.8 or 102.2	2.78	3.89	4.11	4.26	4.37	4.54	4.65	4.73	4.82	4.93	5.19
97.6 or 102.4	2.75	3.84	4.05	4.20	4.31	4.47	4.58	4.67	4.76	4.86	5.12
97.4 or 102.6	2.71	3.79	4.00	4.14	4.25	4.41	4.52	4.60	4.69	4.80	5.05
97.2 or 102.8	2.67	3.73	3.94	4.08	4.19	4.35	4.45	4.53	4.63	4.73	4.98
97.0 or 103.0	2.63	3.68	3.88	4.03	4.13	4.29	4.39	4.47	4.56	4.66	4.91
96.8 or 103.2	2.59	3.62	3.82	3.97	4.07	4.22	4.33	4.40	4.49	4.59	4.84
96.6 or 103.4	2.55	3.57	3.77	3.91	4.01	4.16	4.26	4.34	4.42	4.52	4.76
96.4 or 103.6	2.51	3.52	3.71	3.85	3.95	4.10	4.20	4.27	4.36	4.46	4.69
96.2 or 103.8	2.47	3.46	3.65	3.79	3.89	4.03	4.13	4.21	4.29	4.39	4.62
96.0 or 104.0	2.43	3.41	3.60	3.73	3.83	3.97	4.07	4.14	4.22	4.32	4.55
95.8 or 104.2	2.40	3.35	3.54	3.67	3.77	3.91	4.00	4.08	4.16	4.25	4.48
95.6 or 104.4	2.36	3.30	3.48	3.61	3.71	3.84	3.94	4.01	4.09	4.18	4.40
95.4 or 104.6	2.32	3.24	3.43	3.55	3.65	3.78	3.87	3.95	4.02	4.11	4.33
95.2 or 104.8	2.28	3.19	3.37	3.49	3.58	3.72	3.81	3.88	3.96	4.04	4.26
95.0 or 105.0	2.24	3.13	3.31	3.43	3.52	3.66	3.75	3.81	3.89	3.97	4.19
94.8 or 105.2	2.20	3.08	3.25	3.37	3.46	3.59	3.68	3.75	3.82	3.91	4.11
94.6 or 105.4	2.16	3.03	3.20	3.31	3.40	3.53	3.61	3.68	3.75	3.84	4.04
94.4 or 105.6	2.12	2.97	3.14	3.25	3.34	3.47	3.55	3.61	3.69	3.77	3.97
94.2 or 105.8	2.09	2.92	3.08	3.20	3.28	3.40	3.49	3.55	3.62	3.70	3.90
94.0 or 106.0	2.05	2.86	3.02	3.13	3.22	3.34	3.42	3.48	3.55	3.63	3.82
93.8 or 106.2	2.01	2.81	2.97	3.08	3.16	3.27	3.36	3.42	3.48	3.56	3.75
93.6 or 106.4	1.97	2.75	2.91	3.02	3.10	3.21	3.29	3.35	3.42	3.49	3.68
93.4 or 106.6	1.93	2.70	2.85	2.96	3.04	3.15	3.23	3.28	3.35	3.42	3.61
93.2 or 106.8	1.89	2.65	2.79	2.90	2.97	3.08	3.16	3.22	3.28	3.36	3.53
93.0 or 107.0	1.85	2.59	2.74	2.84	2.91	3.02	3.10	3.15	3.21	3.29	3.46
92.8 or 107.2	1.81	2.54	2.68	2.78	2.85	2.96	3.03	3.09	3.15	3.22	3.39
92.6 or 107.4	1.77	2.48	2.62	2.72	2.79	2.89	2.96	3.02	3.08	3.15	3.32
92.4 or 107.6	1.74	2.43	2.56	2.66	2.73	2.83	2.90	2.95	3.01	3.08	3.24
92.2 or 107.8	1.70	2.37	2.51	2.60	2.67	2.77	2.84	2.89	2.94	3.01	3.17
92.0 or 108.0	1.66	2.32	2.45	2.54	2.61	2.70	2.77	2.82	2.88	2.94	3.10
91.8 or 108.2	1.62	2.26	2.39	2.48	2.55	2.64	2.71	2.75	2.81	2.87	3.02
91.6 or 108.4	1.58	2.21	2.33	2.42	2.48	2.58	2.64	2.69	2.74	2.80	2.95
91.4 or 108.6	1.54	2.16	2.27	2.36	2.42	2.51	2.58	2.62	2.67	2.73	2.88
91.2 or 108.8	1.50	2.10	2.22	2.30	2.36	2.45	2.51	2.55	2.61	2.66	2.81
91.0 or 109.0	1.46	2.05	2.16	2.24	2.30	2.39	2.44	2.49	2.54	2.60	2.73
90.8 or 109.2	1.42	1.99	2.10	2.18	2.24	2.32	2.38	2.42	2.47	2.53	2.66
90.6 or 109.4	1.38	1.94	2.04	2.12	2.18	2.26	2.31	2.36	2.40	2.46	2.59
90.4 or 109.6	1.34	1.88	1.99	2.06	2.12	2.19	2.25	2.29	2.34	2.39	2.51
90.2 or 109.8	1.31	1.83	1.93	2.00	2.05	2.13	2.18	2.22	2.27	2.32	2.44
90.0 or 110.0	1.27	1.77	1.87	1.94	1.99	2.07	2.12	2.16	2.20	2.25	2.37

5.1.11.1 Two examples of acceptance limit tables for Sampling Plan 2 are provided below. These two sampling plans were selected based on material given in two papers (7, 8) published by an ISPE Blend Uniformity/Content Uniformity (BUCU) group that became active after the FDA withdrew a process validation guidance. ISPE has made available information regarding various activities of the group.<sup>8</sup> Table 6 and

Table 7 contain information available from the ISPE. 9 Both tables were created using a confidence level of C = 90 % and a LB = 95 % and assume a target value of 100 %LC. Table 6 applies to a sampling plan with 20 locations with 3 results per location (20 × 3) and Table 7 applies to 40 locations with 3 results per location. The between location and within location standard deviations start at 0.1 %LC and increment by 0.1 %LC up to the maximum possible range on the overall mean.

<sup>8</sup> https://ispe.org/search?keys=BUCU

<sup>&</sup>lt;sup>9</sup> https://ispe.org/initiatives/blend-uniformity-content-uniformity/tools/sampling



TABLE 6 Sampling Plan 2 (20 Locations: 3 Results at Each Location) Acceptance Limits on Overall Mean (%LC) for T = 100 %LC, C = 90 %, LB = 95 %LC

						Sta	ındard De	viation of	Location I	Means (%l	_C)					
SE (9/1-C)	0	).1	C	).2	0	).3	0	.4	0	.5	0	1.6	0	.7	C	).8
(%LC)	LL	UL														
0.1	84.0	116.0	84.4	115.6	84.8	115.2	85.2	114.8	85.6	114.4	86.0	114.0	86.4	113.6	86.8	113.2
0.2	84.2	115.8	84.5	115.5	84.8	115.2	85.2	114.8	85.6	114.4	86.0	114.0	86.4	113.6	86.8	113.2
0.3	84.4	115.6	84.6	115.4	84.9	115.1	85.3	114.7	85.7	114.3	86.1	113.9	86.5	113.5	86.8	113.2
0.4	84.7	115.3	84.8	115.2	85.1	114.9	85.4	114.6	85.8	114.2	86.1	113.9	86.5	113.5	86.9	113.1
0.5	84.9	115.1	85.0	115.0	85.3	114.7	85.5	114.5	85.9	114.1	86.2	113.8	86.6	113.4	87.0	113.0
0.6	85.1	114.9	85.3	114.7	85.5	114.5	85.7	114.3	86.0	114.0	86.3	113.7	86.7	113.3	87.1	112.9
0.7	85.4	114.6	85.5	114.5 114.3	85.7 85.9	114.3	85.9	114.1 113.9	86.2 86.3	113.8 113.7	86.5	113.5 113.4	86.8 86.9	113.2 113.1	87.2 87.3	112.8 112.7
0.8 0.9	85.6 85.9	114.4 114.1	85.7 86.0	114.3	86.1	114.1 113.9	86.1 86.3	113.9	86.5	113.7	86.6 86.8	113.4	87.1	112.9	87.3 87.4	112.7
1.0	86.1	113.9	86.2	113.8	86.4	113.9	86.5	113.7	86.7	113.3	87.0	113.2	87.1	112.8	87.5	112.5
1.1	86.4	113.6	86.5	113.5	86.6	113.4	86.8	113.2	86.9	113.1	87.2	112.8	87.4	112.6	87.7	112.3
1.2	86.6	113.4	86.7	113.3	86.8	113.2	87.0	113.0	87.2	112.8	87.4	112.6	87.6	112.4	87.9	112.1
1.3	86.9	113.1	87.0	113.0	87.1	112.9	87.2	112.8	87.4	112.6	87.6	112.4	87.8	112.2	88.1	111.9
1.4	87.1	112.9	87.2	112.8	87.3	112.7	87.5	112.5	87.6	112.4	87.8	112.2	88.0	112.0	88.2	111.8
1.5	87.4	112.6	87.5	112.5	87.6	112.4	87.7	112.3	87.9	112.1	88.0	112.0	88.2	111.8	88.4	111.6
1.6	87.6	112.4	87.7	112.3	87.8	112.2	87.9	112.1	88.1	111.9	88.2	111.8	88.4	111.6	88.6	111.4
1.7	87.9	112.1	88.0	112.0	88.1	111.9	88.2	111.8	88.3	111.7	88.5	111.5	88.7	111.3	88.9	111.1
1.8	88.1	111.9	88.2	111.8	88.3	111.7	88.4	111.6	88.6	111.4	88.7	111.3	88.9	111.1	89.1	110.9
1.9	88.4	111.6	88.5	111.5	88.6	111.4	88.7	111.3	88.8	111.2	88.9	111.1	89.1	110.9	89.3	110.7
2.0	88.7	111.3 111.1	88.7	111.3	88.8	111.2	88.9	111.1 110.8	89.0 89.3	111.0 110.7	89.2	110.8	89.3 89.6	110.7	89.5 89.7	110.5 110.3
2.1 2.2	88.9 89.2	111.1	89.0 89.2	111.0 110.8	89.1 89.3	110.9 110.7	89.2 89.4	110.8	89.5	110.7	89.4 89.7	110.6 110.3	89.8	110.4 110.2	90.0	110.3
2.3	89.4	110.6	89.5	110.5	89.6	110.7	89.7	110.3	89.8	110.3	89.9	110.3	90.0	110.2	90.2	109.8
2.4	89.7	110.3	89.7	110.3	89.8	110.4	89.9	110.1	90.0	110.2	90.1	109.9	90.3	109.7	90.4	109.6
2.5	89.9	110.1	90.0	110.0	90.1	109.9	90.2	109.8	90.3	109.7	90.4	109.6	90.5	109.5	90.7	109.3
2.6	90.2	109.8	90.2	109.8	90.3	109.7	90.4	109.6	90.5	109.5	90.6	109.4	90.8	109.2	90.9	109.1
2.7	90.4	109.6	90.5	109.5	90.6	109.4	90.7	109.3	90.8	109.2	90.9	109.1	91.0	109.0	91.1	108.9
2.8	90.7	109.3	90.7	109.3	90.8	109.2	90.9	109.1	91.0	109.0	91.1	108.9	91.2	108.8	91.4	108.6
2.9	90.9	109.1	91.0	109.0	91.1	108.9	91.2	108.8	91.3	108.7	91.4	108.6	91.5	108.5	91.6	108.4
3.0	91.2	108.8	91.2	108.8	91.3	108.7	91.4	108.6	91.5	108.5	91.6	108.4	91.7	108.3	91.9	108.1
3.1	91.4	108.6	91.5	108.5	91.6	108.4	91.7	108.3	91.8	108.2	91.9	108.1	92.0	108.0	92.1	107.9
3.2	91.7	108.3	91.7	108.3	91.8	108.2	91.9	108.1	92.0	108.0	92.1	107.9	92.2	107.8	92.3	107.7
3.3 3.4	91.9 92.2	108.1 107.8	92.0 92.2	108.0 107.8	92.1 92.3	107.9 107.7	92.2 92.4	107.8 107.6	92.3 92.5	107.7 107.5	92.4 92.6	107.6 107.4	92.5 92.7	107.5 107.3	92.6 92.8	107.4 107.2
3.5	92.4	107.6	92.5	107.5	92.6	107.7	92.7	107.3	92.8	107.3	92.9	107.4	93.0	107.3	93.1	107.2
3.6	92.7	107.3	92.7	107.3	92.8	107.4	92.9	107.1	93.0	107.2	93.1	106.9	93.2	106.8	93.3	106.7
3.7	92.9	107.1	93.0	107.0	93.1	106.9	93.2	106.8	93.3	106.7	93.4	106.6	93.5	106.5	93.6	106.4
3.8	93.2	106.8	93.3	106.7	93.3	106.7	93.4	106.6	93.5	106.5	93.6	106.4	93.7	106.3	93.8	106.2
3.9	93.4	106.6	93.5	106.5	93.6	106.4	93.7	106.3	93.8	106.2	93.8	106.2	94.0	106.0	94.1	105.9
4.0	93.7	106.3	93.8	106.2	93.8	106.2	93.9	106.1	94.0	106.0	94.1	105.9	94.2	105.8	94.3	105.7
4.1	93.9	106.1	94.0	106.0	94.1	105.9	94.2	105.8	94.3	105.7	94.3	105.7	94.5	105.5	94.6	105.4
4.2	94.2	105.8	94.3	105.7	94.3	105.7	94.4	105.6	94.5	105.5	94.6	105.4	94.7	105.3	94.8	105.2
4.3	94.4	105.6	94.5	105.5	94.6	105.4	94.7	105.3	94.8	105.2	94.9	105.1	95.0	105.0	95.1	104.9
4.4	94.7	105.3	94.8	105.2	94.8	105.2	94.9	105.1	95.0	105.0	95.1	104.9	95.2	104.8	95.3	104.7
4.5	95.0	105.0	95.0	105.0	95.1	104.9	95.2	104.8	95.3	104.7	95.4	104.6	95.5	104.5	95.6	104.4
4.6	95.2	104.8	95.3	104.7	95.4	104.6	95.4	104.6	95.5	104.5	95.6	104.4	95.7	104.3	95.8	104.2
4.7 4.8	95.5 95.7	104.5 104.3	95.5 95.8	104.5 104.2	95.6 95.9	104.4 104.1	95.7 95.9	104.3 104.1	95.8 96.0	104.2 104.0	95.9 96.1	104.1 103.9	96.0 96.2	104.0 103.8	96.1 96.3	103.9 103.7
4.9	96.0	104.3	96.0	104.2	96.1	103.9	96.2	103.8	96.3	104.0	96.4	103.9	96.5	103.5	96.6	103.7
5.0	96.2	104.0	96.3	104.0	96.4	103.9	96.4	103.6	96.5	103.7	96.6	103.4	96.7	103.3	96.8	103.4
5.1	96.5	103.5	96.6	103.7	96.6	103.4	96.7	103.3	96.8	103.3	96.9	103.4	97.0	103.0	97.1	103.2
5.2	96.7	103.3	96.8	103.2	96.9	103.1	97.0	103.0	97.0	103.0	97.1	102.9	97.2	102.8	97.3	102.7
5.3	97.0	103.0	97.1	102.9	97.1	102.9	97.2	102.8	97.3	102.7	97.4	102.6	97.5	102.5	97.6	102.4
5.4	97.3	102.7	97.3	102.7	97.4	102.6	97.5	102.5	97.6	102.4	97.6	102.4	97.7	102.3	97.8	102.2
5.5	97.5	102.5	97.6	102.4	97.7	102.3	97.7	102.3	97.8	102.2	97.9	102.1	98.0	102.0	98.1	101.9
5.6	97.8	102.2	97.8	102.2	97.9	102.1	98.0	102.0	98.1	101.9	98.2	101.8	98.3	101.7	98.4	101.6
5.7	98.1	101.9	98.1	101.9	98.2	101.8	98.3	101.7	98.4	101.6	98.4	101.6	98.5	101.5	98.6	101.4
5.8	98.4	101.6	98.4	101.6	98.5	101.5	98.6	101.4	98.7	101.3	98.7	101.3	98.8	101.2	98.9	101.1
5.9	98.7	101.3	98.8	101.2	98.8	101.2	98.9	101.1	99.0	101.0	99.1	100.9	99.2	100.8	99.3	100.7
6.0	99.1	100.9	99.2	100.8	99.3	100.7	99.4	100.6	99.5	100.5	99.6	100.4	99.7	100.3	99.9	100.1



TABLE 6 Continued

						Sta	ndard De	viation of	ocation N	Jeans (%)	C)					
SE	0	.9	1	.0	1	.1		.2		.3		.4	1.	5	1	.6
(%LC)	LL	UL	LL '	UL	LL '	UL	LL '	UL	LL .	UL	LL '	UL	LL	UL	LL '	UL
0.1	87.2	112.8	87.6	112.4	88.0	112.0	88.4	111.6	88.8	111.2	89.2	110.8	89.6	110.4	90.0	110.0
0.2	87.2	112.8	87.6	112.4	88.0	112.0	88.4	111.6	88.8	111.2	89.2	110.8	89.6	110.4	90.0	110.0
0.3	87.2	112.8	87.6	112.4	88.0	112.0	88.4	111.6	88.8	111.2	89.2	110.8	89.6	110.4	90.0	110.0
0.4	87.3	112.7	87.7	112.3	88.1	111.9	88.5	111.5	88.9	111.1	89.3	110.7	89.7	110.3	90.1	109.9
0.5	87.4	112.6	87.7	112.3	88.1	111.9	88.5	111.5	88.9	111.1	89.3	110.7	89.7	110.3	90.1	109.9
0.6	87.4	112.6	87.8	112.2	88.2	111.8	88.6	111.4	89.0	111.0	89.4	110.6	89.7	110.3	90.1	109.9
0.7 0.8	87.5 87.6	112.5 112.4	87.9 88.0	112.1 112.0	88.3 88.3	111.7 111.7	88.6 88.7	111.4 111.3	89.0 89.1	111.0 110.9	89.4 89.5	110.6 110.5	89.8 89.9	110.2 110.1	90.2 90.2	109.8 109.8
0.8	87.7	112.4	88.1	111.9	88.4	111.6	88.8	111.2	89.2	110.8	89.6	110.3	89.9	110.1	90.2	109.7
1.0	87.9	112.1	88.2	111.8	88.5	111.5	88.9	111.1	89.3	110.7	89.6	110.4	90.0	110.0	90.4	109.6
1.1	88.0	112.0	88.3	111.7	88.7	111.3	89.0	111.0	89.4	110.6	89.7	110.3	90.1	109.9	90.5	109.5
1.2	88.2	111.8	88.5	111.5	88.8	111.2	89.1	110.9	89.5	110.5	89.8	110.2	90.2	109.8	90.6	109.4
1.3	88.3	111.7	88.6	111.4	88.9	111.1	89.3	110.7	89.6	110.4	89.9	110.1	90.3	109.7	90.7	109.3
1.4	88.5	111.5	88.8	111.2	89.1	110.9	89.4	110.6	89.7	110.3	90.1	109.9	90.4	109.6	90.8	109.2
1.5	88.7	111.3	89.0	111.0	89.2	110.8	89.5	110.5	89.9	110.1	90.2	109.8	90.5	109.5	90.9	109.1
1.6 1.7	88.9 89.1	111.1 110.9	89.1 89.3	110.9 110.7	89.4 89.6	110.6 110.4	89.7 89.9	110.3 110.1	90.0 90.2	110.0 109.8	90.3 90.5	109.7 109.5	90.6 90.8	109.4 109.2	91.0 91.1	109.0 108.9
1.8	89.3	110.7	89.5	110.7	89.8	110.4	90.0	110.0	90.3	109.7	90.6	109.4	90.9	109.1	91.2	108.8
1.9	89.5	110.5	89.7	110.3	90.0	110.0	90.2	109.8	90.5	109.5	90.8	109.2	91.1	108.9	91.4	108.6
2.0	89.7	110.3	89.9	110.1	90.1	109.9	90.4	109.6	90.7	109.3	90.9	109.1	91.2	108.8	91.5	108.5
2.1	89.9	110.1	90.1	109.9	90.3	109.7	90.6	109.4	90.8	109.2	91.1	108.9	91.4	108.6	91.7	108.3
2.2	90.1	109.9	90.3	109.7	90.6	109.4	90.8	109.2	91.0	109.0	91.3	108.7	91.6	108.4	91.9	108.1
2.3	90.4	109.6	90.6	109.4	90.8	109.2	91.0	109.0	91.2	108.8	91.5	108.5	91.7	108.3	92.0	108.0
2.4 2.5	90.6 90.8	109.4 109.2	90.8 91.0	109.2 109.0	91.0 91.2	109.0 108.8	91.2 91.4	108.8 108.6	91.4 91.6	108.6 108.4	91.7 91.9	108.3 108.1	91.9 92.1	108.1 107.9	92.2 92.4	107.8 107.6
2.6	91.1	109.2	91.0	108.8	91.4	108.6	91.4	108.4	91.8	108.4	92.1	100.1	92.1	107.9	92.4	107.6
2.7	91.3	108.7	91.5	108.5	91.6	108.4	91.8	108.2	92.0	108.0	92.3	107.7	92.5	107.5	92.7	107.3
2.8	91.5	108.5	91.7	108.3	91.9	108.1	92.0	108.0	92.2	107.8	92.5	107.5	92.7	107.3	92.9	107.1
2.9	91.8	108.2	91.9	108.1	92.1	107.9	92.3	107.7	92.5	107.5	92.7	107.3	92.9	107.1	93.1	106.9
3.0	92.0	108.0	92.2	107.8	92.3	107.7	92.5	107.5	92.7	107.3	92.9	107.1	93.1	106.9	93.3	106.7
3.1	92.2	107.8	92.4	107.6	92.5	107.5	92.7	107.3	92.9	107.1	93.1	106.9	93.3	106.7	93.5	106.5
3.2	92.5	107.5	92.6	107.4	92.8	107.2	92.9	107.1	93.1	106.9	93.3	106.7	93.5	106.5	93.7	106.3
3.3 3.4	92.7 93.0	107.3 107.0	92.9 93.1	107.1 106.9	93.0 93.3	107.0 106.7	93.2 93.4	106.8 106.6	93.4 93.6	106.6 106.4	93.5 93.8	106.5 106.2	93.7 94.0	106.3 106.0	93.9 94.2	106.1 105.8
3.5	93.2	106.8	93.3	106.7	93.5	106.7	93.6	106.4	93.8	106.4	94.0	106.2	94.2	105.8	94.4	105.6
3.6	93.4	106.6	93.6	106.4	93.7	106.3	93.9	106.1	94.0	106.0	94.2	105.8	94.4	105.6	94.6	105.4
3.7	93.7	106.3	93.8	106.2	94.0	106.0	94.1	105.9	94.3	105.7	94.4	105.6	94.6	105.4	94.8	105.2
3.8	93.9	106.1	94.1	105.9	94.2	105.8	94.4	105.6	94.5	105.5	94.7	105.3	94.8	105.2	95.0	105.0
3.9	94.2	105.8	94.3	105.7	94.4	105.6	94.6	105.4	94.7	105.3	94.9	105.1	95.1	104.9	95.3	104.7
4.0	94.4	105.6	94.6	105.4	94.7 94.9	105.3	94.8	105.2	95.0	105.0	95.1	104.9	95.3	104.7	95.5	104.5
4.1 4.2	94.7 94.9	105.3 105.1	94.8 95.0	105.2 105.0	94.9 95.2	105.1 104.8	95.1 95.3	104.9 104.7	95.2 95.5	104.8 104.5	95.4 95.6	104.6 104.4	95.5 95.8	104.5 104.2	95.7 95.9	104.3 104.1
4.3	95.2	104.8	95.3	104.7	95.4	104.6	95.6	104.7	95.7	104.3	95.8	104.4	96.0	104.2	96.2	103.8
4.4	95.4	104.6	95.5	104.5	95.7	104.3	95.8	104.2	95.9	104.1	96.1	103.9	96.2	103.8	96.4	103.6
4.5	95.7	104.3	95.8	104.2	95.9	104.1	96.0	104.0	96.2	103.8	96.3	103.7	96.5	103.5	96.6	103.4
4.6	95.9	104.1	96.0	104.0	96.2	103.8	96.3	103.7	96.4	103.6	96.6	103.4	96.7	103.3	96.9	103.1
4.7	96.2	103.8	96.3	103.7	96.4	103.6	96.5	103.5	96.7	103.3	96.8	103.2	97.0	103.0	97.1	102.9
4.8	96.4	103.6	96.5	103.5	96.6	103.4	96.8	103.2	96.9	103.1	97.0	103.0	97.2	102.8	97.3	102.7
4.9 5.0	96.7	103.3	96.8	103.2	96.9	103.1	97.0	103.0	97.2 97.4	102.8	97.3	102.7	97.4 97.7	102.6	97.6	102.4
5.0 5.1	96.9 97.2	103.1 102.8	97.0 97.3	103.0 102.7	97.1 97.4	102.9 102.6	97.3 97.5	102.7 102.5	97.4 97.6	102.6 102.4	97.5 97.8	102.5 102.2	97.7 97.9	102.3 102.1	97.8 98.1	102.2 101.9
5.2	97.4	102.6	97.5	102.7	97.6	102.4	97.8	102.3	97.9	102.4	98.0	102.2	98.2	101.8	98.3	101.3
5.3	97.7	102.3	97.8	102.2	97.9	102.1	98.0	102.0	98.1	101.9	98.3	101.7	98.4	101.6	98.6	101.4
5.4	97.9	102.1	98.0	102.0	98.2	101.8	98.3	101.7	98.4	101.6	98.5	101.5	98.7	101.3	98.8	101.2
5.5	98.2	101.8	98.3	101.7	98.4	101.6	98.5	101.5	98.7	101.3	98.8	101.2	98.9	101.1	99.1	100.9
5.6	98.5	101.5	98.6	101.4	98.7	101.3	98.8	101.2	98.9	101.1	99.1	100.9	99.2	100.8	99.4	100.6
5.7	98.7	101.3	98.9	101.1	99.0	101.0	99.1	100.9	99.2	100.8	99.4	100.6	99.6	100.4	99.7	100.3
5.8 5.9	99.1	100.9 100.6	99.2	100.8	99.3	100.7	99.4 99.9	100.6	99.6	100.4	99.8	100.2	100.0	100.0	-	
5.9	99.4	0.001	99.6	100.4	99.7	100.3	99.9	100.1								



TABLE 6 Continued

						Ct	TABLE		ntinued	Moone (0/1	C)					
SE -	- 1	.7	-	1.8	1			eviation of 1		Means (%L !.1		2.2	0	.3	2	.4
(%LC) -	LL '	UL	' '	UL	<u>'</u>	.9 UL		UL		UL		UL		.s UL		UL
0.1	90.4	109.6	90.8	109.2	91.2	108.8	91.6	108.4	92.0	108.0	92.4	107.6	92.8	107.2	93.2	106.8
0.2	90.4	109.6	90.8	109.2	91.2	108.8	91.6	108.4	92.0	108.0	92.4	107.6	92.8	107.2	93.2	106.8
0.3	90.4	109.6	90.8	109.2	91.2	108.8	91.6	108.4	92.0	108.0	92.4	107.6	92.8	107.2	93.3	106.7
0.4	90.5	109.5	90.9	109.1	91.3	108.7	91.7	108.3	92.1	107.9	92.5	107.5	92.9	107.1	93.3	106.7
0.5	90.5	109.5	90.9	109.1	91.3	108.7	91.7	108.3	92.1	107.9	92.5	107.5	92.9	107.1	93.3	106.7
0.6	90.5 90.6	109.5 109.4	90.9 91.0	109.1 109.0	91.3 91.4	108.7	91.7 91.8	108.3 108.2	92.1 92.2	107.9 107.8	92.5 92.6	107.5	92.9 93.0	107.1 107.0	93.3 93.4	106.7 106.6
0.7 0.8	90.6	109.4	91.0	109.0	91.4	108.6 108.6	91.8	108.2	92.2	107.8	92.6	107.4 107.4	93.0	107.0	93.4	106.6
0.9	90.7	109.3	91.1	108.9	91.5	108.5	91.9	108.1	92.3	107.7	92.6	107.4	93.0	107.0	93.4	106.6
1.0	90.8	109.2	91.1	108.9	91.5	108.5	91.9	108.1	92.3	107.7	92.7	107.3	93.1	106.9	93.5	106.5
1.1	90.8	109.2	91.2	108.8	91.6	108.4	92.0	108.0	92.4	107.6	92.8	107.2	93.1	106.9	93.5	106.5
1.2	90.9	109.1	91.3	108.7	91.7	108.3	92.1	107.9	92.4	107.6	92.8	107.2	93.2	106.8	93.6	106.4
1.3	91.0	109.0	91.4	108.6	91.8	108.2	92.1	107.9	92.5	107.5	92.9	107.1	93.3	106.7	93.7	106.3
1.4	91.1	108.9	91.5	108.5	91.8	108.2	92.2	107.8	92.6	107.4	93.0	107.0	93.3	106.7	93.7	106.3
1.5	91.2	108.8	91.6	108.4	91.9	108.1	92.3	107.7	92.7	107.3	93.1	106.9	93.4	106.6	93.8	106.2
1.6	91.3	108.7	91.7	108.3	92.0	108.0	92.4	107.6	92.8	107.2	93.1	106.9	93.5	106.5	93.9	106.1
1.7 1.8	91.5 91.6	108.5 108.4	91.8 91.9	108.2 108.1	92.1 92.3	107.9 107.7	92.5 92.6	107.5 107.4	92.9 93.0	107.1 107.0	93.2 93.3	106.8 106.7	93.6 93.7	106.4 106.3	94.0 94.1	106.0 105.9
1.9	91.7	108.4	92.0	108.0	92.4	107.7	92.7	107.4	93.1	106.9	93.4	106.7	93.8	106.2	94.1	105.9
2.0	91.9	108.1	92.2	107.8	92.5	107.5	92.8	107.2	93.2	106.8	93.5	106.5	93.9	106.1	94.3	105.7
2.1	92.0	108.0	92.3	107.7	92.6	107.4	93.0	107.0	93.3	106.7	93.7	106.3	94.0	106.0	94.4	105.6
2.2	92.2	107.8	92.5	107.5	92.8	107.2	93.1	106.9	93.4	106.6	93.8	106.2	94.1	105.9	94.5	105.5
2.3	92.3	107.7	92.6	107.4	92.9	107.1	93.2	106.8	93.6	106.4	93.9	106.1	94.2	105.8	94.6	105.4
2.4	92.5	107.5	92.8	107.2	93.1	106.9	93.4	106.6	93.7	106.3	94.0	106.0	94.4	105.6	94.7	105.3
2.5	92.6	107.4	92.9	107.1	93.2	106.8	93.5	106.5	93.8	106.2	94.2	105.8	94.5	105.5	94.8	105.2
2.6	92.8	107.2	93.1	106.9	93.4	106.6	93.7	106.3	94.0	106.0	94.3	105.7	94.6	105.4	95.0	105.0
2.7	93.0	107.0	93.3	106.7	93.6	106.4	93.8	106.2	94.1	105.9	94.5	105.5	94.8	105.2	95.1	104.9
2.8 2.9	93.2 93.4	106.8 106.6	93.4 93.6	106.6 106.4	93.7 93.9	106.3 106.1	94.0 94.2	106.0 105.8	94.3 94.5	105.7 105.5	94.6 94.8	105.4 105.2	94.9 95.1	105.1 104.9	95.2 95.4	104.8 104.6
3.0	93.6	106.4	93.8	106.4	94.1	105.9	94.4	105.6	94.6	105.4	94.9	105.2	95.2	104.8	95.5	104.5
3.1	93.8	106.2	94.0	106.0	94.3	105.7	94.5	105.5	94.8	105.2	95.1	104.9	95.4	104.6	95.7	104.3
3.2	94.0	106.0	94.2	105.8	94.5	105.5	94.7	105.3	95.0	105.0	95.3	104.7	95.6	104.4	95.9	104.1
3.3	94.2	105.8	94.4	105.6	94.6	105.4	94.9	105.1	95.2	104.8	95.4	104.6	95.7	104.3	96.0	104.0
3.4	94.4	105.6	94.6	105.4	94.8	105.2	95.1	104.9	95.3	104.7	95.6	104.4	95.9	104.1	96.2	103.8
3.5	94.6	105.4	94.8	105.2	95.0	105.0	95.3	104.7	95.5	104.5	95.8	104.2	96.1	103.9	96.4	103.6
3.6	94.8	105.2	95.0	105.0	95.2	104.8	95.5	104.5	95.7	104.3	96.0	104.0	96.3	103.7	96.5	103.5
3.7	95.0	105.0	95.2	104.8	95.4	104.6	95.7	104.3	95.9	104.1	96.2	103.8	96.4	103.6	96.7	103.3
3.8 3.9	95.2 95.5	104.8 104.5	95.4 95.7	104.6 104.3	95.7 95.9	104.3 104.1	95.9 96.1	104.1 103.9	96.1 96.3	103.9 103.7	96.4 96.6	103.6 103.4	96.6 96.8	103.4 103.2	96.9 97.1	103.1 102.9
4.0	95.7	104.3	95.9	104.5	96.1	103.9	96.3	103.3	96.5	103.7	96.8	103.4	97.0	103.2	97.3	102.7
4.1	95.9	104.1	96.1	103.9	96.3	103.7	96.5	103.5	96.7	103.3	97.0	103.0	97.2	102.8	97.5	102.5
4.2	96.1	103.9	96.3	103.7	96.5	103.5	96.7	103.3	96.9	103.1	97.2	102.8	97.4	102.6	97.7	102.3
4.3	96.4	103.6	96.5	103.5	96.7	103.3	96.9	103.1	97.2	102.8	97.4	102.6	97.6	102.4	97.8	102.2
4.4	96.6	103.4	96.8	103.2	97.0	103.0	97.2	102.8	97.4	102.6	97.6	102.4	97.8	102.2	98.0	102.0
4.5	96.8	103.2	97.0	103.0	97.2	102.8	97.4	102.6	97.6	102.4	97.8	102.2	98.0	102.0	98.3	101.7
4.6	97.0	103.0	97.2	102.8	97.4	102.6	97.6	102.4	97.8	102.2	98.0	102.0	98.2	101.8	98.5	101.5
4.7	97.3	102.7	97.5	102.5	97.6	102.4	97.8	102.2	98.0	102.0	98.2	101.8	98.4	101.6	98.7	101.3
4.8	97.5	102.5	97.7	102.3	97.9	102.1	98.0	102.0	98.2	101.8	98.4	101.6	98.7	101.3	98.9	101.1
4.9 5.0	97.7 98.0	102.3 102.0	97.9 98.2	102.1 101.8	98.1 98.3	101.9 101.7	98.3 98.5	101.7 101.5	98.5 98.7	101.5 101.3	98.7 98.9	101.3 101.1	98.9 99.1	101.1 100.9	99.1 99.3	100.9 100.7
5.1	98.2	102.0	98.4	101.6	98.6	101.7	98.7	101.3	98.9	101.3	99.1	101.1	99.1	100.9	99.6	100.7
5.2	98.5	101.5	98.6	101.4	98.8	101.4	99.0	101.0	99.2	100.8	99.4	100.5	99.6	100.7	99.8	100.4
5.3	98.7	101.3	98.9	101.1	99.1	100.9	99.2	100.8	99.4	100.6	99.6	100.4	99.9	100.1		
5.4	99.0	101.0	99.1	100.9	99.3	100.7	99.5	100.5	99.7	100.3	99.9	100.1				
5.5	99.2	100.8	99.4	100.6	99.6	100.4	99.8	100.2								
5.6	99.6	100.4	99.7	100.3	100.0	100.0										
5.7	99.9	100.1														



TABLE 6 Continued

							IABLE		ntinued		-					
SE -								viation of								
(%LC) .	2	2.5	2	2.6	2	2.7	2	.8	2	.9	3	3.0	3	.1	3	.2
	LL	UL														
0.1	93.6	106.4	94.0	106.0	94.4	105.6	94.8	105.2	95.3	104.7	95.7	104.3	96.1	103.9	96.5	103.5
0.2	93.6	106.4	94.0	106.0	94.4	105.6	94.9	105.1	95.3	104.7	95.7	104.3	96.1	103.9	96.5	103.5
0.3	93.7	106.3	94.1	105.9	94.5	105.5	94.9	105.1	95.3	104.7	95.7	104.3	96.1	103.9	96.5	103.5
0.4	93.7	106.3	94.1	105.9	94.5	105.5	94.9	105.1	95.3	104.7	95.7	104.3	96.1	103.9	96.5	103.5
0.5	93.7	106.3	94.1	105.9	94.5	105.5	94.9	105.1	95.3	104.7	95.7	104.3	96.1	103.9	96.5	103.5
0.6	93.7	106.3	94.1	105.9	94.5	105.5	94.9	105.1	95.3	104.7	95.7	104.3	96.1	103.9	96.5	103.5
0.7	93.8	106.2	94.2	105.8	94.6	105.4	95.0	105.0	95.4	104.6	95.8	104.2	96.2	103.8	96.6	103.4
0.8	93.8	106.2	94.2	105.8	94.6	105.4	95.0	105.0	95.4	104.6	95.8	104.2	96.2	103.8	96.6	103.4
0.9	93.8	106.2	94.2	105.8	94.6	105.4	95.0	105.0	95.4	104.6	95.8	104.2	96.2	103.8	96.6	103.4
1.0	93.9	106.1	94.3	105.7	94.7	105.3	95.1	104.9	95.5	104.5	95.9	104.1	96.3	103.7	96.7	103.3
1.1	93.9	106.1	94.3	105.7	94.7	105.3	95.1	104.9	95.5	104.5	95.9	104.1	96.3	103.7	96.7	103.3
1.2	94.0	106.0	94.4	105.6	94.8	105.2	95.2	104.8	95.6	104.4	96.0	104.0	96.3	103.7	96.7	103.3
1.3	94.0	106.0	94.4	105.6	94.8	105.2	95.2	104.8	95.6	104.4	96.0	104.0	96.4	103.6	96.8	103.2
1.4	94.1	105.9	94.5	105.5	94.9	105.1	95.3	104.7	95.7	104.3	96.1	103.9	96.5	103.5	96.8	103.2
1.5	94.2	105.8	94.6	105.4	95.0	105.0	95.3	104.7	95.7	104.3	96.1	103.9	96.5	103.5	96.9	103.1
1.6	94.3	105.7	94.6	105.4	95.0	105.0	95.4	104.6	95.8	104.2	96.2	103.8	96.6	103.4	97.0	103.0
1.7	94.3	105.7	94.7	105.3	95.1	104.9	95.5	104.5	95.9	104.1	96.3	103.7	96.6	103.4	97.0	103.0
1.8	94.4	105.6	94.8	105.2	95.2	104.8	95.6	104.4	95.9	104.1	96.3	103.7	96.7	103.3	97.1	102.9
1.9 2.0	94.5	105.5	94.9	105.1	95.3	104.7	95.6	104.4	96.0	104.0	96.4	103.6	96.8	103.2	97.2	102.8
	94.6	105.4	95.0	105.0	95.4	104.6	95.7	104.3	96.1	103.9	96.5	103.5	96.9	103.1	97.2	102.8
2.1 2.2	94.7 94.8	105.3	95.1 95.2	104.9 104.8	95.4 95.5	104.6 104.5	95.8 95.9	104.2 104.1	96.2 96.3	103.8 103.7	96.6 96.7	103.4 103.3	96.9 97.0	103.1 103.0	97.3 97.4	102.7 102.6
		105.2 105.1						104.1						103.0		102.6
2.3 2.4	94.9 95.1	103.1	95.3 95.4	104.7 104.6	95.7 95.8	104.3 104.2	96.0 96.1	104.0	96.4 96.5	103.6 103.5	96.7 96.8	103.3 103.2	97.1 97.2	102.9	97.5 97.6	102.5
2.4	95.1	104.9	95.4 95.5	104.5	95.6 95.9	104.2	96.1	103.9	96.6	103.5	96.9	103.2	97.2	102.6	97.6	102.4
2.5	95.2 95.3	104.6	95.5 95.6	104.5	96.0	104.1	96.2	103.6	96.7	103.4	97.1	103.1	97.3 97.4	102.7	97.7	102.3
2.7	95.4	104.7	95.8	104.4	96.1	103.9	96.5	103.7	96.8	103.3	97.1	102.8	97.5	102.5	97.9	102.2
2.8	95.6	104.4	95.9	104.2	96.2	103.8	96.6	103.4	96.9	103.2	97.3	102.7	97.6	102.3	98.0	102.1
2.9	95.7	104.3	96.0	104.0	96.4	103.6	96.7	103.3	97.0	103.0	97.4	102.7	97.7	102.3	98.1	101.9
3.0	95.9	104.1	96.2	103.8	96.5	103.5	96.8	103.2	97.2	102.8	97.5	102.5	97.9	102.1	98.2	101.8
3.1	96.0	104.0	96.3	103.7	96.6	103.4	97.0	103.0	97.3	102.7	97.6	102.4	98.0	102.0	98.3	101.7
3.2	96.2	103.8	96.5	103.5	96.8	103.2	97.1	102.9	97.4	102.6	97.8	102.2	98.1	101.9	98.5	101.7
3.3	96.3	103.7	96.6	103.4	96.9	103.1	97.3	102.7	97.6	102.4	97.9	102.1	98.2	101.8	98.6	101.4
3.4	96.5	103.5	96.8	103.2	97.1	102.9	97.4	102.6	97.7	102.3	98.0	102.0	98.4	101.6	98.7	101.3
3.5	96.6	103.4	96.9	103.1	97.2	102.8	97.6	102.4	97.9	102.1	98.2	101.8	98.5	101.5	98.9	101.1
3.6	96.8	103.2	97.1	102.9	97.4	102.6	97.7	102.3	98.0	102.0	98.3	101.7	98.7	101.3	99.0	101.0
3.7	97.0	103.0	97.3	102.7	97.6	102.4	97.9	102.1	98.2	101.8	98.5	101.5	98.8	101.2	99.1	100.9
3.8	97.2	102.8	97.4	102.6	97.7	102.3	98.0	102.0	98.3	101.7	98.6	101.4	99.0	101.0	99.3	100.7
3.9	97.3	102.7	97.6	102.4	97.9	102.1	98.2	101.8	98.5	101.5	98.8	101.2	99.1	100.9	99.4	100.6
4.0	97.5	102.5	97.8	102.2	98.1	101.9	98.4	101.6	98.7	101.3	99.0	101.0	99.3	100.7	99.6	100.4
4.1	97.7	102.3	98.0	102.0	98.3	101.7	98.5	101.5	98.8	101.2	99.1	100.9	99.4	100.6	99.8	100.2
4.2	97.9	102.1	98.2	101.8	98.4	101.6	98.7	101.3	99.0	101.0	99.3	100.7	99.6	100.4	99.9	100.1
4.3	98.1	101.9	98.4	101.6	98.6	101.4	98.9	101.1	99.2	100.8	99.5	100.5	99.8	100.2		
4.4	98.3	101.7	98.5	101.5	98.8	101.2	99.1	100.9	99.4	100.6	99.7	100.3	100.0	100.0		
4.5	98.5	101.5	98.7	101.3	99.0	101.0	99.3	100.7	99.6	100.4	99.9	100.1				
4.6	98.7	101.3	98.9	101.1	99.2	100.8	99.5	100.5	99.8	100.2						
4.7	98.9	101.1	99.2	100.8	99.4	100.6	99.7	100.3	100.0	100.0						
4.8	99.1	100.9	99.4	100.6	99.6	100.4	99.9	100.1								
4.9	99.3	100.7	99.6	100.4	99.9	100.1										
5.0	99.6	100.4	99.8	100.2												
5.1	99.8	100.2														



TABLE 6 Continued

							TABLE	<b>6</b> CO	ntinued							
						Sta	andard De	viation of	Location N	∕leans (%l	_C)					
SE - (%LC) -	3	.3	3	.4	3	.5	3	.6	3	.7	3	.8	3	3.9	4	.0
(/8LO) -	LL	UL	LL	UL	LL	UL	LL	UL	LL	UL	LL	UL	LL	UL	LL	UL
0.1	96.9	103.1	97.3	102.7	97.7	102.3	98.1	101.9	98.5	101.5	98.9	101.1	99.3	100.7	99.7	100.3
0.2	96.9	103.1	97.3	102.7	97.7	102.3	98.1	101.9	98.5	101.5	98.9	101.1	99.3	100.7	99.7	100.3
0.3	96.9	103.1	97.3	102.7	97.7	102.3	98.1	101.9	98.5	101.5	98.9	101.1	99.3	100.7	99.7	100.3
0.4	96.9	103.1	97.3	102.7	97.7	102.3	98.1	101.9	98.5	101.5	98.9	101.1	99.3	100.7	99.8	100.2
0.5	96.9	103.1	97.3	102.7	97.7	102.3	98.1	101.9	98.5	101.5	99.0	101.0	99.4	100.6	99.8	100.2
0.6	96.9	103.1	97.3	102.7	97.7	102.3	98.2	101.8	98.6	101.4	99.0	101.0	99.4	100.6	99.8	100.2
0.7	97.0	103.0	97.4	102.6	97.8	102.2	98.2	101.8	98.6	101.4	99.0	101.0	99.4	100.6	99.8	100.2
0.8	97.0	103.0	97.4	102.6	97.8	102.2	98.2	101.8	98.6	101.4	99.0	101.0	99.4	100.6	99.8	100.2
0.9	97.0	103.0	97.4	102.6	97.8	102.2	98.2	101.8	98.6	101.4	99.0	101.0	99.5	100.5	99.9	100.1
1.0	97.1	102.9	97.5	102.5	97.9	102.1	98.3	101.7	98.7	101.3	99.1	100.9	99.5	100.5	99.9	100.1
1.1	97.1	102.9	97.5	102.5	97.9	102.1	98.3	101.7	98.7	101.3	99.1	100.9	99.5	100.5	99.9	100.1
1.2	97.1	102.9	97.5	102.5	97.9	102.1	98.3	101.7	98.7	101.3	99.1	100.9	99.6	100.4		
1.3	97.2	102.8	97.6	102.4	98.0	102.0	98.4	101.6	98.8	101.2	99.2	100.8	99.6	100.4		
1.4	97.2	102.8	97.6	102.4	98.0	102.0	98.4	101.6	98.8	101.2	99.2	100.8	99.6	100.4		
1.5	97.3	102.7	97.7	102.3	98.1	101.9	98.5	101.5	98.9	101.1	99.3	100.7	99.7	100.3		
1.6	97.4	102.6	97.7	102.3	98.1	101.9	98.5	101.5	98.9	101.1	99.3	100.7	99.7	100.3		
1.7	97.4	102.6	97.8	102.2	98.2	101.8	98.6	101.4	99.0	101.0	99.4	100.6	99.8	100.2		
1.8	97.5	102.5	97.9	102.1	98.3	101.7	98.7	101.3	99.0	101.0	99.4	100.6	99.8	100.2		
1.9	97.6	102.4	97.9	102.1	98.3	101.7	98.7	101.3	99.1	100.9	99.5	100.5	99.9	100.1		
2.0	97.6	102.4	98.0	102.0	98.4	101.6	98.8	101.2	99.2	100.8	99.6	100.4				
2.1	97.7	102.3	98.1	101.9	98.5	101.5	98.9	101.1	99.2	100.8	99.6	100.4				
2.2	97.8	102.2	98.2	101.8	98.5	101.5	98.9	101.1	99.3	100.7	99.7	100.3				
2.3	97.9	102.1	98.2	101.8	98.6	101.4	99.0	101.0	99.4	100.6	99.8	100.2				
2.4	98.0	102.0	98.3	101.7	98.7	101.3	99.1	100.9	99.5	100.5	99.9	100.1				
2.5	98.1	101.9	98.4	101.6	98.8	101.2	99.2	100.8	99.6	100.4						
2.6	98.1	101.9	98.5	101.5	98.9	101.1	99.3	100.7	99.7	100.3						
2.7	98.2	101.8	98.6	101.4	99.0	101.0	99.4	100.6	99.7	100.3						
2.8	98.4	101.6	98.7	101.3	99.1	100.9	99.5	100.5	99.8	100.2			•			
2.9	98.5	101.5	98.8	101.2	99.2	100.8	99.6	100.4	99.9	100.1			•			
3.0	98.6	101.4	98.9	101.1	99.3	100.7	99.7	100.3	100.0	100.0			•			
3.1	98.7	101.3	99.0	101.0	99.4	100.6	99.8	100.2		•			•			
3.2	98.8	101.2	99.2	100.8	99.5	100.5	99.9	100.1								
3.3	98.9	101.1	99.3	100.7	99.6	100.4	100.0	100.0		•			•			
3.4	99.1	100.9	99.4	100.6	99.8	100.2										
3.5	99.2	100.8	99.5	100.5	99.9	100.1										
3.6	99.3	100.7	99.7	100.3	100.0	100.0										
3.7	99.5	100.5	99.8	100.2												
3.8	99.6	100.4	100.0	100.0												
3.9	99.8	100.2													•	
4.0	99.9	100.1				•						•		•		



TABLE 7 Sampling Plan 2 (40 Locations: 3 Results at Each Location) Acceptance Limits on Overall Mean (%LC) for T = 100 %LC, C = 90 %, LB = 95 %LC

								eviation of			_C)					
SE -	0	.1		).2	0	.3		).4		.5		.6	0	).7	0	.8
(%LC) -	LL	UL														
0.1	84.0	116.0	84.3	115.7	84.6	115.4	85.0	115.0	85.3	114.7	85.6	114.4	86.0	114.0	86.3	113.7
0.1	84.1	115.9	84.4	115.7	84.7	115.4	85.0	115.0	85.3	114.7	85.7	114.3	86.0	114.0	86.4	113.6
0.3	84.3	115.7	84.5	115.5	84.8	115.2	85.1	114.9	85.4	114.6	85.7	114.3	86.1	113.9	86.4	113.6
0.4	84.6	115.4	84.7	115.3	84.9	115.1	85.2	114.8	85.5	114.5	85.8	114.2	86.1	113.9	86.5	113.5
0.5	84.8	115.2	84.9	115.1	85.1	114.9	85.3	114.7	85.6	114.4	85.9	114.1	86.2	113.8	86.5	113.5
0.6 0.7	85.0 85.3	115.0 114.7	85.1 85.4	114.9 114.6	85.3 85.5	114.7 114.5	85.5 85.7	114.5 114.3	85.8 85.9	114.2 114.1	86.0 86.2	114.0 113.8	86.3 86.4	113.7 113.6	86.6 86.7	113.4 113.3
0.7	85.5	114.7	85.6	114.4	85.7	114.3	85.9	114.3	86.1	113.9	86.3	113.7	86.6	113.4	86.9	113.3
0.9	85.7	114.3	85.8	114.2	85.9	114.1	86.1	113.9	86.3	113.7	86.5	113.5	86.7	113.3	87.0	113.0
1.0	86.0	114.0	86.0	114.0	86.1	113.9	86.3	113.7	86.5	113.5	86.7	113.3	86.9	113.1	87.1	112.9
1.1	86.2	113.8	86.3	113.7	86.4	113.6	86.5	113.5	86.7	113.3	86.8	113.2	87.1	112.9	87.3	112.7
1.2	86.4	113.6	86.5	113.5	86.6	113.4	86.7	113.3	86.9	113.1	87.0	113.0	87.2	112.8	87.5	112.5
1.3 1.4	86.7 86.9	113.3 113.1	86.7 87.0	113.3 113.0	86.8 87.1	113.2 112.9	86.9 87.2	113.1 112.8	87.1 87.3	112.9 112.7	87.2 87.4	112.8 112.6	87.4 87.6	112.6 112.4	87.6 87.8	112.4 112.2
1.5	87.1	112.9	87.2	112.8	87.3	112.7	87.4	112.6	87.5	112.5	87.7	112.3	87.8	112.2	88.0	112.0
1.6	87.4	112.6	87.4	112.6	87.5	112.5	87.6	112.4	87.7	112.3	87.9	112.1	88.0	112.0	88.2	111.8
1.7	87.6	112.4	87.7	112.3	87.7	112.3	87.8	112.2	88.0	112.0	88.1	111.9	88.2	111.8	88.4	111.6
1.8	87.8	112.2	87.9	112.1	88.0	112.0	88.1	111.9	88.2	111.8	88.3	111.7	88.4	111.6	88.6	111.4
1.9 2.0	88.1 88.3	111.9 111.7	88.1 88.4	111.9 111.6	88.2 88.4	111.8 111.6	88.3 88.5	111.7 111.5	88.4 88.6	111.6 111.4	88.5 88.7	111.5 111.3	88.7 88.9	111.3 111.1	88.8 89.0	111.2 111.0
2.0	88.6	111.7	88.6	111.6	88.7	111.8	88.8	111.5	88.9	111.4	89.0	111.0	89.1	110.9	89.0 89.2	110.8
2.2	88.8	111.2	88.8	111.2	88.9	111.1	89.0	111.0	89.1	110.9	89.2	110.8	89.3	110.3	89.5	110.5
2.3	89.0	111.0	89.1	110.9	89.1	110.9	89.2	110.8	89.3	110.7	89.4	110.6	89.5	110.5	89.7	110.3
2.4	89.3	110.7	89.3	110.7	89.4	110.6	89.5	110.5	89.5	110.5	89.6	110.4	89.8	110.2	89.9	110.1
2.5	89.5	110.5	89.5	110.5	89.6	110.4	89.7	110.3	89.8	110.2	89.9	110.1	90.0	110.0	90.1	109.9
2.6 2.7	89.7 90.0	110.3 110.0	89.8 90.0	110.2 110.0	89.8 90.1	110.2 109.9	89.9 90.2	110.1 109.8	90.0 90.2	110.0 109.8	90.1 90.3	109.9 109.7	90.2 90.4	109.8 109.6	90.3 90.6	109.7 109.4
2.8	90.0	109.8	90.3	109.7	90.1	109.5	90.4	109.6	90.5	109.5	90.6	109.7	90.7	109.0	90.8	109.4
2.9	90.4	109.6	90.5	109.5	90.5	109.5	90.6	109.4	90.7	109.3	90.8	109.2	90.9	109.1	91.0	109.0
3.0	90.7	109.3	90.7	109.3	90.8	109.2	90.9	109.1	90.9	109.1	91.0	109.0	91.1	108.9	91.2	108.8
3.1	90.9	109.1	91.0	109.0	91.0	109.0	91.1	108.9	91.2	108.8	91.3	108.7	91.3	108.7	91.5	108.5
3.2 3.3	91.1 91.4	108.9	91.2 91.4	108.8	91.3 91.5	108.7 108.5	91.3 91.6	108.7 108.4	91.4 91.6	108.6 108.4	91.5 91.7	108.5	91.6	108.4 108.2	91.7	108.3 108.1
3.4	91.4	108.6 108.4	91.4	108.6 108.3	91.5	108.3	91.8	108.4	91.0	108.4	91.7	108.3 108.1	91.8 92.0	108.2	91.9 92.1	100.1
3.5	91.9	108.1	91.9	108.1	92.0	108.0	92.0	108.0	92.1	107.9	92.2	107.8	92.3	107.7	92.4	107.6
3.6	92.1	107.9	92.1	107.9	92.2	107.8	92.3	107.7	92.3	107.7	92.4	107.6	92.5	107.5	92.6	107.4
3.7	92.3	107.7	92.4	107.6	92.4	107.6	92.5	107.5	92.6	107.4	92.6	107.4	92.7	107.3	92.8	107.2
3.8	92.6	107.4	92.6	107.4	92.7	107.3	92.7	107.3	92.8	107.2	92.9	107.1	93.0	107.0	93.1	106.9
3.9 4.0	92.8 93.0	107.2 107.0	92.8 93.1	107.2 106.9	92.9 93.1	107.1 106.9	93.0 93.2	107.0 106.8	93.0 93.3	107.0 106.7	93.1 93.3	106.9 106.7	93.2 93.4	106.8 106.6	93.3 93.5	106.7 106.5
4.1	93.3	106.7	93.3	106.7	93.4	106.6	93.4	106.6	93.5	106.5	93.6	106.4	93.7	106.3	93.7	106.3
4.2	93.5	106.5	93.6	106.4	93.6	106.4	93.7	106.3	93.7	106.3	93.8	106.2	93.9	106.1	94.0	106.0
4.3	93.7	106.3	93.8	106.2	93.8	106.2	93.9	106.1	94.0	106.0	94.0	106.0	94.1	105.9	94.2	105.8
4.4	94.0	106.0	94.0	106.0	94.1	105.9	94.1	105.9	94.2	105.8	94.3	105.7	94.4	105.6	94.4	105.6
4.5 4.6	94.2 94.5	105.8 105.5	94.3 94.5	105.7 105.5	94.3 94.6	105.7 105.4	94.4 94.6	105.6 105.4	94.4 94.7	105.6 105.3	94.5 94.8	105.5 105.2	94.6 94.8	105.4 105.2	94.7 94.9	105.3 105.1
4.6 4.7	94.5 94.7	105.5	94.5 94.7	105.5	94.6	105.4	94.6	105.4	94.7	105.3	94.8 95.0	105.2	94.8 95.1	105.2	94.9 95.1	105.1
4.8	94.9	105.1	95.0	105.0	95.0	105.2	95.1	104.9	95.2	104.8	95.2	104.8	95.3	104.7	95.4	104.6
4.9	95.2	104.8	95.2	104.8	95.3	104.7	95.3	104.7	95.4	104.6	95.5	104.5	95.5	104.5	95.6	104.4
5.0	95.4	104.6	95.5	104.5	95.5	104.5	95.6	104.4	95.6	104.4	95.7	104.3	95.8	104.2	95.8	104.2
5.1	95.6	104.4	95.7	104.3	95.7	104.3	95.8	104.2	95.9	104.1	95.9	104.1	96.0	104.0	96.1	103.9
5.2 5.3	95.9 96.1	104.1 103.9	95.9 96.2	104.1 103.8	96.0 96.2	104.0 103.8	96.0 96.3	104.0 103.7	96.1 96.3	103.9 103.7	96.2 96.4	103.8 103.6	96.2 96.5	103.8 103.5	96.3 96.6	103.7 103.4
5.4	96.1	103.9	96.4	103.6	96.2 96.5	103.6	96.5	103.7	96.6	103.7	96.4	103.6	96.7	103.3	96.8	103.4
5.5	96.6	103.4	96.7	103.3	96.7	103.3	96.8	103.2	96.8	103.2	96.9	103.1	97.0	103.0	97.0	103.0
5.6	96.8	103.2	96.9	103.1	96.9	103.1	97.0	103.0	97.1	102.9	97.1	102.9	97.2	102.8	97.3	102.7
5.7	97.1	102.9	97.1	102.9	97.2	102.8	97.2	102.8	97.3	102.7	97.4	102.6	97.4	102.6	97.5	102.5
5.8	97.3	102.7	97.4	102.6	97.4 07.7	102.6	97.5 07.7	102.5	97.5	102.5	97.6	102.4	97.7	102.3	97.7	102.3
5.9 6.0	97.6 97.8	102.4 102.2	97.6 97.9	102.4 102.1	97.7 97.9	102.3 102.1	97.7 98.0	102.3 102.0	97.8 98.0	102.2 102.0	97.8 98.1	102.2 101.9	97.9 98.2	102.1 101.8	98.0 98.2	102.0 101.8
6.1	98.1	101.9	98.1	101.9	98.2	102.1	98.2	102.0	98.3	102.0	98.4	101.6	98.4	101.6	98.5	101.5
6.2	98.4	101.6	98.4	101.6	98.5	101.5	98.5	101.5	98.6	101.4	98.7	101.3	98.7	101.3	98.8	101.2
6.3	98.7	101.3	98.7	101.3	98.8	101.2	98.9	101.1	98.9	101.1	99.0	101.0	99.1	100.9	99.2	100.8
6.4	99.1	100.9	99.1	100.9	99.2	100.8	99.3	100.7	99.4	100.6	99.5	100.5	99.6	100.4	99.7	100.3



TABLE 7 Continued

						Sta	ndard De	viation of I	ocation I	Means (%I	C)					
SE -	0	).9	1	1.0	1	.1		.2		.3		.4	1	.5	1	.6
(%LC) -	LL	UL														
0.1	86.7	113.3	87.0	113.0	87.4	112.6	87.7	112.3	88.1	111.9	88.4	111.6	88.8	111.2	89.1	110.9
0.2	86.7	113.3	87.0	113.0	87.4	112.6	87.7	112.3	88.1	111.9	88.4	111.6	88.8	111.2	89.1	110.9
0.3	86.7	113.3	87.1	112.9	87.4	112.6	87.8	112.2	88.1	111.9	88.5	111.5	88.8	111.2	89.1	110.9
0.4	86.8 86.9	113.2	87.1 87.2	112.9 112.8	87.5 87.5	112.5	87.8 87.9	112.2 112.1	88.1 88.2	111.9 111.8	88.5 88.5	111.5 111.5	88.8 88.9	111.2 111.1	89.2 89.2	110.8
0.5 0.6	86.9	113.1 113.1	87.2 87.3	112.7	87.6	112.5 112.4	87.9	112.1	88.2	111.8	88.6	111.5	88.9	111.1	89.3	110.8 110.7
0.7	87.0	113.0	87.3	112.7	87.7	112.3	88.0	112.0	88.3	111.7	88.6	111.4	89.0	111.0	89.3	110.7
0.8	87.1	112.9	87.4	112.6	87.8	112.2	88.1	111.9	88.4	111.6	88.7	111.3	89.0	111.0	89.4	110.6
0.9	87.3	112.7	87.6	112.4	87.9	112.1	88.2	111.8	88.5	111.5	88.8	111.2	89.1	110.9	89.4	110.6
1.0	87.4	112.6	87.7 87.8	112.3	88.0 88.1	112.0	88.3 88.4	111.7	88.6 88.7	111.4	88.9	111.1	89.2	110.8 110.7	89.5 89.6	110.5
1.1 1.2	87.5 87.7	112.5 112.3	88.0	112.2 112.0	88.2	111.9 111.8	88.5	111.6 111.5	88.8	111.3 111.2	89.0 89.1	111.0 110.9	89.3 89.4	110.7	89.7	110.4 110.3
1.3	87.9	112.1	88.1	111.9	88.4	111.6	88.6	111.4	88.9	111.1	89.2	110.8	89.5	110.5	89.8	110.2
1.4	88.0	112.0	88.3	111.7	88.5	111.5	88.8	111.2	89.0	111.0	89.3	110.7	89.6	110.4	89.9	110.1
1.5	88.2	111.8	88.4	111.6	88.7	111.3	88.9	111.1	89.2	110.8	89.5	110.5	89.7	110.3	90.0	110.0
1.6	88.4	111.6	88.6	111.4	88.8	111.2	89.1	110.9	89.3	110.7	89.6	110.4	89.9	110.1	90.2	109.8
1.7 1.8	88.6 88.8	111.4 111.2	88.8 89.0	111.2 111.0	89.0 89.2	111.0 110.8	89.2 89.4	110.8 110.6	89.5 89.6	110.5 110.4	89.7 89.9	110.3 110.1	90.0 90.2	110.0 109.8	90.3 90.4	109.7 109.6
1.9	89.0	111.0	89.2	110.8	89.4	110.6	89.6	110.4	89.8	110.4	90.0	110.1	90.3	109.7	90.6	109.4
2.0	89.2	110.8	89.4	110.6	89.6	110.4	89.8	110.2	90.0	110.0	90.2	109.8	90.5	109.5	90.7	109.3
2.1	89.4	110.6	89.6	110.4	89.7	110.3	89.9	110.1	90.2	109.8	90.4	109.6	90.6	109.4	90.9	109.1
2.2	89.6	110.4	89.8	110.2	89.9	110.1	90.1	109.9	90.3	109.7	90.6	109.4	90.8	109.2	91.0	109.0
2.3 2.4	89.8 90.0	110.2 110.0	90.0 90.2	110.0 109.8	90.1 90.3	109.9 109.7	90.3 90.5	109.7 109.5	90.5 90.7	109.5 109.3	90.7 90.9	109.3 109.1	91.0 91.1	109.0 108.9	91.2 91.4	108.8 108.6
2.5	90.2	109.8	90.4	109.6	90.5	109.5	90.7	109.3	90.9	109.1	91.1	108.9	91.3	108.7	91.5	108.5
2.6	90.5	109.5	90.6	109.4	90.8	109.2	90.9	109.1	91.1	108.9	91.3	108.7	91.5	108.5	91.7	108.3
2.7	90.7	109.3	90.8	109.2	91.0	109.0	91.1	108.9	91.3	108.7	91.5	108.5	91.7	108.3	91.9	108.1
2.8	90.9	109.1	91.0	109.0	91.2	108.8	91.3	108.7	91.5	108.5	91.7	108.3	91.9	108.1	92.1	107.9
2.9 3.0	91.1 91.3	108.9 108.7	91.3 91.5	108.7 108.5	91.4 91.6	108.6 108.4	91.5 91.8	108.5 108.2	91.7 91.9	108.3 108.1	91.9 92.1	108.1 107.9	92.1 92.3	107.9 107.7	92.3 92.5	107.7 107.5
3.1	91.6	108.4	91.7	108.3	91.8	108.2	92.0	108.0	92.1	107.9	92.3	107.7	92.5	107.5	92.7	107.3
3.2	91.8	108.2	91.9	108.1	92.0	108.0	92.2	107.8	92.3	107.7	92.5	107.5	92.7	107.3	92.8	107.2
3.3	92.0	108.0	92.1	107.9	92.3	107.7	92.4	107.6	92.5	107.5	92.7	107.3	92.9	107.1	93.0	107.0
3.4	92.2	107.8	92.4	107.6	92.5	107.5	92.6	107.4	92.8	107.2	92.9	107.1	93.1	106.9	93.2	106.8
3.5 3.6	92.5 92.7	107.5 107.3	92.6 92.8	107.4 107.2	92.7 92.9	107.3 107.1	92.8 93.1	107.2 106.9	93.0 93.2	107.0 106.8	93.1 93.3	106.9 106.7	93.3 93.5	106.7 106.5	93.5 93.7	106.5 106.3
3.7	92.9	107.1	93.0	107.0	93.2	106.8	93.3	106.7	93.4	106.6	93.6	106.4	93.7	106.3	93.9	106.1
3.8	93.2	106.8	93.3	106.7	93.4	106.6	93.5	106.5	93.6	106.4	93.8	106.2	93.9	106.1	94.1	105.9
3.9	93.4	106.6	93.5	106.5	93.6	106.4	93.7	106.3	93.9	106.1	94.0	106.0	94.1	105.9	94.3	105.7
4.0	93.6 93.8	106.4 106.2	93.7 93.9	106.3 106.1	93.8 94.1	106.2 105.9	93.9 94.2	106.1 105.8	94.1 94.3	105.9 105.7	94.2 94.4	105.8 105.6	94.3 94.6	105.7 105.4	94.5 94.7	105.5 105.3
4.1 4.2	94.1	105.2	94.2	105.8	94.1	105.9	94.4	105.6	94.5	105.7	94.6	105.4	94.8	105.4	94.7	105.3
4.3	94.3	105.7	94.4	105.6	94.5	105.5	94.6	105.4	94.7	105.3	94.9	105.1	95.0	105.0	95.1	104.9
4.4	94.5	105.5	94.6	105.4	94.7	105.3	94.8	105.2	95.0	105.0	95.1	104.9	95.2	104.8	95.4	104.6
4.5	94.8	105.2	94.9	105.1	95.0	105.0	95.1	104.9	95.2	104.8	95.3	104.7	95.4	104.6	95.6	104.4
4.6 4.7	95.0 95.2	105.0 104.8	95.1 95.3	104.9 104.7	95.2 95.4	104.8 104.6	95.3 95.5	104.7 104.5	95.4 95.6	104.6 104.4	95.5 95.8	104.5 104.2	95.7 95.9	104.3 104.1	95.8 96.0	104.2 104.0
4.7	95.5	104.5	95.6	104.7	95.7	104.0	95.8	104.3	95.9	104.4	96.0	104.2	96.1	103.9	96.2	103.8
4.9	95.7	104.3	95.8	104.2	95.9	104.1	96.0	104.0	96.1	103.9	96.2	103.8	96.3	103.7	96.5	103.5
5.0	95.9	104.1	96.0	104.0	96.1	103.9	96.2	103.8	96.3	103.7	96.4	103.6	96.6	103.4	96.7	103.3
5.1	96.2	103.8	96.3	103.7	96.4	103.6	96.5	103.5	96.6	103.4	96.7	103.3	96.8	103.2	96.9	103.1
5.2 5.3	96.4 96.6	103.6 103.4	96.5 96.7	103.5 103.3	96.6 96.8	103.4 103.2	96.7 96.9	103.3 103.1	96.8 97.0	103.2 103.0	96.9 97.1	103.1 102.9	97.0 97.2	103.0 102.8	97.1 97.4	102.9 102.6
5.4	96.9	103.4	97.0	103.3	97.1	103.2	97.1	103.1	97.3	103.0	97.1	102.9	97.5	102.5	97.4	102.0
5.5	97.1	102.9	97.2	102.8	97.3	102.7	97.4	102.6	97.5	102.5	97.6	102.4	97.7	102.3	97.8	102.2
5.6	97.3	102.7	97.4	102.6	97.5	102.5	97.6	102.4	97.7	102.3	97.8	102.2	97.9	102.1	98.1	101.9
5.7	97.6	102.4	97.7	102.3	97.8	102.2	97.9	102.1	98.0	102.0	98.1	101.9	98.2	101.8	98.3	101.7
5.8 5.9	97.8 98.1	102.2 101.9	97.9 98.2	102.1 101.8	98.0 98.2	102.0 101.8	98.1 98.3	101.9 101.7	98.2 98.4	101.8 101.6	98.3 98.6	101.7 101.4	98.4 98.7	101.6 101.3	98.5 98.8	101.5 101.2
6.0	98.3	101.9	98.4	101.6	98.5	101.5	98.6	101.7	98.7	101.8	98.8	101.4	98.9	101.3	99.1	100.9
6.1	98.6	101.4	98.7	101.3	98.8	101.2	98.9	101.1	99.0	101.0	99.1	100.9	99.3	100.7	99.4	100.6
6.2	98.9	101.1	99.0	101.0	99.1	100.9	99.2	100.8	99.4	100.6	99.5	100.5	99.7	100.3	99.9	100.1
6.3	99.3	100.7	99.4	100.6	99.5	100.5	99.7	100.3	99.9	100.1						
6.4	99.9	100.1								-		-				



TABLE 7 Continued

						04-	TABLI		ntinued	A (0/ I	0)					
SE -	1	.7	- 1	1.8	- 1	Standard Deviation of Location Means (%LC)  1.9 2.0 2.1 2.2 2.3							. 2	2.4		
(%LC) -	'	./ UL	' LL	UL	LL '	.9 UL	LL	UL								
0.1	89.5	110.5	89.8	110.2	90.1	109.9	90.5	109.5	90.8	109.2	91.2	108.8	91.5	108.5	91.9	108.1
0.2	89.5	110.5	89.8	110.2	90.2	109.8	90.5	109.5	90.9	109.1	91.2	108.8	91.5	108.5	91.9	108.1
0.3	89.5	110.5	89.8	110.2	90.2	109.8	90.5	109.5	90.9	109.1	91.2	108.8	91.6	108.4	91.9	108.1
0.4	89.5	110.5	89.9	110.1	90.2	109.8	90.5	109.5	90.9	109.1	91.2	108.8	91.6	108.4	91.9	108.1
0.5	89.6	110.4	89.9	110.1	90.2	109.8	90.6	109.4	90.9	109.1	91.3	108.7	91.6	108.4	92.0	108.0
0.6	89.6	110.4	89.9	110.1	90.3	109.7	90.6	109.4	91.0	109.0	91.3	108.7	91.6	108.4	92.0	108.0
0.7 0.8	89.6 89.7	110.4 110.3	90.0 90.0	110.0 110.0	90.3 90.4	109.7 109.6	90.7 90.7	109.3 109.3	91.0 91.0	109.0 109.0	91.3 91.4	108.7 108.6	91.7 91.7	108.3 108.3	92.0 92.1	108.0 107.9
0.9	89.8	110.3	90.1	109.9	90.4	109.6	90.8	109.2	91.1	108.9	91.4	108.6	91.8	108.2	92.1	107.9
1.0	89.8	110.2	90.2	109.8	90.5	109.5	90.8	109.2	91.2	108.8	91.5	108.5	91.8	108.2	92.2	107.8
1.1	89.9	110.1	90.2	109.8	90.6	109.4	90.9	109.1	91.2	108.8	91.6	108.4	91.9	108.1	92.2	107.8
1.2	90.0	110.0	90.3	109.7	90.7	109.3	91.0	109.0	91.3	108.7	91.6	108.4	92.0	108.0	92.3	107.7
1.3	90.1	109.9	90.4	109.6	90.7	109.3	91.1	108.9	91.4	108.6	91.7	108.3	92.0	108.0	92.4	107.6
1.4 1.5	90.2 90.3	109.8 109.7	90.5 90.6	109.5 109.4	90.8 90.9	109.2 109.1	91.1 91.2	108.9 108.8	91.5 91.6	108.5 108.4	91.8 91.9	108.2 108.1	92.1 92.2	107.9 107.8	92.4 92.5	107.6 107.5
1.5	90.3	109.7	90.6	109.4	90.9	109.1	91.2	108.8	91.6	108.4	91.9	108.1	92.2	107.8	92.5 92.6	107.5
1.7	90.6	109.4	90.9	109.1	91.2	108.8	91.5	108.5	91.8	108.2	92.1	107.9	92.4	107.7	92.7	107.4
1.8	90.7	109.3	91.0	109.0	91.3	108.7	91.6	108.4	91.9	108.1	92.2	107.8	92.5	107.5	92.8	107.2
1.9	90.8	109.2	91.1	108.9	91.4	108.6	91.7	108.3	92.0	108.0	92.3	107.7	92.6	107.4	92.9	107.1
2.0	91.0	109.0	91.2	108.8	91.5	108.5	91.8	108.2	92.1	107.9	92.4	107.6	92.7	107.3	93.0	107.0
2.1	91.1	108.9	91.4	108.6	91.7	108.3	91.9	108.1	92.2	107.8	92.5	107.5	92.8	107.2	93.1	106.9
2.2 2.3	91.3 91.4	108.7 108.6	91.5 91.7	108.5 108.3	91.8 91.9	108.2 108.1	92.1 92.2	107.9 107.8	92.3 92.5	107.7 107.5	92.6 92.8	107.4 107.2	92.9 93.0	107.1 107.0	93.2 93.3	106.8 106.7
2.3	91.4	108.4	91.7	108.2	92.1	106.1	92.2	107.6	92.6	107.5	92.9	107.2	93.0	107.0	93.5	106.7
2.5	91.8	108.2	92.0	108.0	92.2	107.8	92.5	107.5	92.8	107.1	93.0	107.0	93.3	106.7	93.6	106.4
2.6	91.9	108.1	92.2	107.8	92.4	107.6	92.7	107.3	92.9	107.1	93.2	106.8	93.4	106.6	93.7	106.3
2.7	92.1	107.9	92.3	107.7	92.6	107.4	92.8	107.2	93.1	106.9	93.3	106.7	93.6	106.4	93.9	106.1
2.8	92.3	107.7	92.5	107.5	92.7	107.3	93.0	107.0	93.2	106.8	93.5	106.5	93.7	106.3	94.0	106.0
2.9	92.5	107.5	92.7	107.3	92.9	107.1	93.1	106.9	93.4	106.6	93.6	106.4	93.9	106.1	94.1	105.9
3.0 3.1	92.7 92.8	107.3 107.2	92.9 93.0	107.1 107.0	93.1 93.3	106.9 106.7	93.3 93.5	106.7 106.5	93.5 93.7	106.5 106.3	93.8 94.0	106.2 106.0	94.0 94.2	106.0 105.8	94.3 94.4	105.7 105.6
3.2	93.0	107.2	93.2	107.0	93.4	106.7	93.7	106.3	93.9	106.3	94.1	105.9	94.4	105.6	94.6	105.4
3.3	93.2	106.8	93.4	106.6	93.6	106.4	93.8	106.2	94.1	105.9	94.3	105.7	94.5	105.5	94.8	105.2
3.4	93.4	106.6	93.6	106.4	93.8	106.2	94.0	106.0	94.2	105.8	94.5	105.5	94.7	105.3	94.9	105.1
3.5	93.6	106.4	93.8	106.2	94.0	106.0	94.2	105.8	94.4	105.6	94.6	105.4	94.9	105.1	95.1	104.9
3.6	93.8	106.2	94.0	106.0	94.2	105.8	94.4	105.6	94.6	105.4	94.8	105.2	95.0	105.0	95.3	104.7
3.7	94.0	106.0	94.2	105.8	94.4	105.6	94.6	105.4	94.8	105.2	95.0 95.2	105.0	95.2	104.8	95.4	104.6
3.8 3.9	94.2 94.4	105.8 105.6	94.4 94.6	105.6 105.4	94.6 94.8	105.4 105.2	94.8 95.0	105.2 105.0	95.0 95.2	105.0 104.8	95.2 95.4	104.8 104.6	95.4 95.6	104.6 104.4	95.6 95.8	104.4 104.2
4.0	94.7	105.3	94.8	105.4	95.0	105.2	95.2	104.8	95.4	104.6	95.6	104.4	95.8	104.4	96.0	104.2
4.1	94.9	105.1	95.0	105.0	95.2	104.8	95.4	104.6	95.6	104.4	95.8	104.2	96.0	104.0	96.2	103.8
4.2	95.1	104.9	95.2	104.8	95.4	104.6	95.6	104.4	95.8	104.2	96.0	104.0	96.2	103.8	96.4	103.6
4.3	95.3	104.7	95.5	104.5	95.6	104.4	95.8	104.2	96.0	104.0	96.2	103.8	96.3	103.7	96.5	103.5
4.4	95.5	104.5	95.7	104.3	95.8	104.2	96.0	104.0	96.2	103.8	96.4	103.6	96.5	103.5	96.7	103.3
4.5 4.6	95.7 95.9	104.3 104.1	95.9 96.1	104.1 103.9	96.0 96.2	104.0 103.8	96.2 96.4	103.8 103.6	96.4 96.6	103.6 103.4	96.6 96.8	103.4 103.2	96.7 96.9	103.3 103.1	96.9 97.1	103.1 102.9
4.6	95.9 96.2	104.1	96.1	103.9	96.2 96.5	103.8	96.4 96.6	103.6	96.8	103.4	96.8	103.2	96.9 97.1	103.1	97.1	102.9
4.8	96.4	103.6	96.5	103.7	96.7	103.3	96.8	103.4	97.0	103.2	97.2	102.8	97.3	102.7	97.5	102.7
4.9	96.6	103.4	96.7	103.3	96.9	103.1	97.0	103.0	97.2	102.8	97.4	102.6	97.6	102.4	97.7	102.3
5.0	96.8	103.2	97.0	103.0	97.1	102.9	97.3	102.7	97.4	102.6	97.6	102.4	97.8	102.2	97.9	102.1
5.1	97.0	103.0	97.2	102.8	97.3	102.7	97.5	102.5	97.6	102.4	97.8	102.2	98.0	102.0	98.1	101.9
5.2	97.3	102.7	97.4	102.6	97.5	102.5	97.7	102.3	97.9	102.1	98.0	102.0	98.2	101.8	98.4	101.6
5.3 5.4	97.5 97.7	102.5	97.6 97.9	102.4	97.8 98.0	102.2	97.9 98.1	102.1	98.1	101.9	98.2 98.4	101.8	98.4 98.6	101.6	98.6	101.4
5.4 5.5	97.7 98.0	102.3 102.0	97.9 98.1	102.1 101.9	98.0 98.2	102.0 101.8	98.1 98.4	101.9 101.6	98.3 98.5	101.7 101.5	98.4 98.7	101.6 101.3	98.6 98.8	101.4 101.2	98.8 99.0	101.2 101.0
5.6	98.2	102.0	98.3	101.5	98.5	101.5	98.6	101.4	98.8	101.3	98.9	101.3	99.1	100.9	99.3	100.7
5.7	98.4	101.6	98.6	101.4	98.7	101.3	98.8	101.2	99.0	101.0	99.2	100.8	99.4	100.6	99.6	100.4
5.8	98.7	101.3	98.8	101.2	98.9	101.1	99.1	100.9	99.3	100.7	99.5	100.5	99.7	100.3	99.9	100.1
5.9	98.9	101.1	99.1	100.9	99.2	100.8	99.4	100.6	99.6	100.4	99.8	100.2				
6.0	99.2	100.8	99.4	100.6	99.6	100.4	99.8	100.2	100.0	100.0		-	-			
6.1	99.6	100.4	99.8	100.2	100.0	100.0	•		•			•	•	•		

TABLE 7 Continued

						04-	TABLE		ntinued	14 (0/1	0)					
SE -	2.5			Standard Deviation of Location Means (%LC) 2.6 2.7 2.8 2.9 3.0 3.1									1		.2	
(%LC) -	LL	UL	LL	UL	LL	./ UL	LL	UL	LL	UL.	LL	UL	LL	UL	LL	UL
0.1	92.2	107.8	92.6	107.4	92.9	107.1	93.3	106.7	93.6	106.4	94.0	106.0	94.3	105.7	94.7	105.3
0.2	92.2	107.8	92.6	107.4	92.9	107.1	93.3	106.7	93.6	106.4	94.0	106.0	94.3	105.7	94.7	105.3
0.3	92.3	107.7	92.6	107.4	92.9	107.1	93.3	106.7	93.6	106.4	94.0	106.0	94.3	105.7	94.7	105.3
0.4	92.3	107.7	92.6	107.4	93.0	107.0	93.3	106.7	93.7	106.3	94.0	106.0	94.4	105.6	94.7	105.3
0.5	92.3	107.7	92.6	107.4	93.0	107.0	93.3	106.7	93.7	106.3	94.0	106.0	94.4	105.6	94.7	105.3
0.6	92.3 92.4	107.7 107.6	92.7 92.7	107.3 107.3	93.0 93.0	107.0 107.0	93.4 93.4	106.6 106.6	93.7 93.7	106.3 106.3	94.0 94.1	106.0 105.9	94.4 94.4	105.6 105.6	94.7 94.8	105.3 105.2
0.7 0.8	92.4	107.6	92.7	107.3	93.0	107.0	93.4	106.6	93.7	106.3	94.1	105.9	94.4	105.6	94.8	105.2
0.9	92.4	107.6	92.8	107.2	93.1	106.9	93.5	106.5	93.8	106.2	94.2	105.8	94.5	105.5	94.8	105.2
1.0	92.5	107.5	92.8	107.2	93.2	106.8	93.5	106.5	93.9	106.1	94.2	105.8	94.5	105.5	94.9	105.1
1.1	92.6	107.4	92.9	107.1	93.2	106.8	93.6	106.4	93.9	106.1	94.2	105.8	94.6	105.4	94.9	105.1
1.2	92.6	107.4	93.0	107.0	93.3	106.7	93.6	106.4	94.0	106.0	94.3	105.7	94.6	105.4	95.0	105.0
1.3	92.7	107.3	93.0	107.0	93.3	106.7	93.7	106.3	94.0	106.0	94.3	105.7	94.7	105.3	95.0	105.0
1.4	92.8	107.2	93.1	106.9	93.4	106.6	93.7	106.3	94.1	105.9	94.4	105.6	94.7	105.3	95.1	104.9
1.5	92.8	107.2	93.2	106.8	93.5	106.5	93.8	106.2	94.1	105.9	94.5	105.5	94.8	105.2	95.1	104.9
1.6	92.9	107.1	93.2	106.8	93.6	106.4	93.9	106.1	94.2	105.8	94.5	105.5	94.9	105.1	95.2	104.8
1.7	93.0	107.0	93.3	106.7	93.6	106.4	94.0	106.0 106.0	94.3	105.7	94.6	105.4	94.9	105.1 105.0	95.3	104.7
1.8 1.9	93.1 93.2	106.9 106.8	93.4 93.5	106.6 106.5	93.7 93.8	106.3 106.2	94.0 94.1	105.0	94.4 94.5	105.6 105.5	94.7 94.8	105.3 105.2	95.0 95.1	105.0	95.3 95.4	104.7 104.6
2.0	93.3	106.7	93.6	106.4	93.9	106.2	94.2	105.8	94.5	105.5	94.9	105.2	95.2	104.8	95.5	104.5
2.1	93.4	106.6	93.7	106.3	94.0	106.0	94.3	105.7	94.6	105.4	95.0	105.0	95.3	104.7	95.6	104.4
2.2	93.5	106.5	93.8	106.2	94.1	105.9	94.4	105.6	94.7	105.3	95.0	105.0	95.4	104.6	95.7	104.3
2.3	93.6	106.4	93.9	106.1	94.2	105.8	94.5	105.5	94.8	105.2	95.1	104.9	95.5	104.5	95.8	104.2
2.4	93.7	106.3	94.0	106.0	94.3	105.7	94.6	105.4	94.9	105.1	95.2	104.8	95.6	104.4	95.9	104.1
2.5	93.9	106.1	94.2	105.8	94.5	105.5	94.8	105.2	95.1	104.9	95.4	104.6	95.7	104.3	96.0	104.0
2.6	94.0	106.0	94.3	105.7	94.6	105.4	94.9	105.1	95.2	104.8	95.5	104.5	95.8	104.2	96.1	103.9
2.7	94.1	105.9	94.4	105.6	94.7	105.3	95.0	105.0	95.3	104.7	95.6	104.4	95.9	104.1	96.2	103.8
2.8	94.3	105.7	94.5	105.5	94.8	105.2	95.1	104.9	95.4	104.6	95.7	104.3	96.0	104.0	96.3	103.7
2.9 3.0	94.4 94.6	105.6 105.4	94.7 94.8	105.3 105.2	95.0 95.1	105.0 104.9	95.2 95.4	104.8 104.6	95.5 95.7	104.5 104.3	95.8 95.9	104.2 104.1	96.1 96.2	103.9 103.8	96.4 96.5	103.6 103.5
3.1	94.7	105.4	95.0	105.2	95.1	104.8	95.5	104.5	95.8	104.3	96.1	103.9	96.4	103.6	96.7	103.3
3.2	94.9	105.1	95.1	104.9	95.4	104.6	95.7	104.3	95.9	104.1	96.2	103.8	96.5	103.5	96.8	103.2
3.3	95.0	105.0	95.3	104.7	95.5	104.5	95.8	104.2	96.1	103.9	96.3	103.7	96.6	103.4	96.9	103.1
3.4	95.2	104.8	95.4	104.6	95.7	104.3	95.9	104.1	96.2	103.8	96.5	103.5	96.8	103.2	97.0	103.0
3.5	95.3	104.7	95.6	104.4	95.8	104.2	96.1	103.9	96.4	103.6	96.6	103.4	96.9	103.1	97.2	102.8
3.6	95.5	104.5	95.7	104.3	96.0	104.0	96.3	103.7	96.5	103.5	96.8	103.2	97.0	103.0	97.3	102.7
3.7	95.7	104.3	95.9	104.1	96.2	103.8	96.4	103.6	96.7	103.3	96.9	103.1	97.2	102.8	97.5	102.5
3.8	95.8	104.2	96.1	103.9	96.3	103.7	96.6	103.4	96.8	103.2	97.1	102.9	97.3	102.7	97.6	102.4
3.9	96.0	104.0	96.3	103.7	96.5	103.5	96.7	103.3	97.0	103.0	97.2	102.8	97.5	102.5	97.8	102.2
4.0 4.1	96.2 96.4	103.8 103.6	96.4 96.6	103.6 103.4	96.7 96.8	103.3 103.2	96.9 97.1	103.1 102.9	97.1 97.3	102.9 102.7	97.4 97.6	102.6 102.4	97.6 97.8	102.4 102.2	97.9 98.1	102.1 101.9
4.2	96.6	103.4	96.8	103.4	97.0	103.2	97.1	102.8	97.5	102.7	97.7	102.4	98.0	102.2	98.2	101.8
4.3	96.8	103.4	97.0	103.2	97.2	103.8	97.4	102.6	97.7	102.3	97.9	102.3	98.1	101.9	98.4	101.6
4.4	96.9	103.1	97.2	102.8	97.4	102.6	97.6	102.4	97.8	102.2	98.1	101.9	98.3	101.7	98.6	101.4
4.5	97.1	102.9	97.3	102.7	97.6	102.4	97.8	102.2	98.0	102.0	98.2	101.8	98.5	101.5	98.7	101.3
4.6	97.3	102.7	97.5	102.5	97.7	102.3	98.0	102.0	98.2	101.8	98.4	101.6	98.6	101.4	98.9	101.1
4.7	97.5	102.5	97.7	102.3	97.9	102.1	98.1	101.9	98.4	101.6	98.6	101.4	98.8	101.2	99.1	100.9
4.8	97.7	102.3	97.9	102.1	98.1	101.9	98.3	101.7	98.6	101.4	98.8	101.2	99.0	101.0	99.3	100.7
4.9	97.9	102.1	98.1	101.9	98.3	101.7	98.5	101.5	98.7	101.3	99.0	101.0	99.2	100.8	99.5	100.5
5.0	98.1	101.9	98.3	101.7	98.5	101.5	98.7	101.3	98.9	101.1	99.2	100.8	99.4	100.6	99.7	100.3
5.1	98.3	101.7	98.5	101.5	98.7	101.3	98.9	101.1	99.2	100.8	99.4	100.6	99.6	100.4	99.9	100.1
5.2	98.5	101.5	98.7	101.3	98.9	101.1	99.1	100.9	99.4	100.6	99.6	100.4	99.9	100.1		
5.3 5.4	98.8	101.2	98.9	101.1	99.2	100.8	99.4	100.6	99.6	100.4	99.9	100.1	•	•	-	•
5.4 5.5	99.0 99.2	101.0 100.8	99.2 99.4	100.8 100.6	99.4 99.7	100.6 100.3	99.6 99.9	100.4 100.1	99.9	100.1		•	•	•	•	•
5.6	99.5	100.5	99.4	100.8	100.0	100.3	99.9				-		•	•		•
5.7	99.8	100.2												•		•



TABLE 7 Continued

							TABLE		ntinued							
C.E.						Sta	andard De	eviation of	Location N	Means (%	LC)					
SE (%LC)	3	3.3		3.1		3.5		3.6		3.7		.8	3.9		4.0	
(//	LL	UL	LL	UL	LL	UL	LL	UL								
0.1	95.0	105.0	95.4	104.6	95.7	104.3	96.1	103.9	96.4	103.6	96.8	103.2	97.1	102.9	97.5	102.5
0.2	95.0	105.0	95.4	104.6	95.7	104.3	96.1	103.9	96.4	103.6	96.8	103.2	97.1	102.9	97.5	102.5
0.3	95.0	105.0	95.4	104.6	95.7	104.3	96.1	103.9	96.4	103.6	96.8	103.2	97.1	102.9	97.5	102.5
0.4	95.0	105.0	95.4	104.6	95.7	104.3	96.1	103.9	96.4	103.6	96.8	103.2	97.1	102.9	97.5	102.5
0.5	95.1	104.9	95.4	104.6	95.8	104.2	96.1	103.9	96.5	103.5	96.8	103.2	97.2	102.8	97.5	102.5
0.6	95.1	104.9	95.4	104.6	95.8	104.2	96.1	103.9	96.5	103.5	96.8	103.2	97.2	102.8	97.5	102.5
0.7	95.1	104.9	95.5	104.5	95.8	104.2	96.2	103.8	96.5	103.5	96.8	103.2	97.2	102.8	97.5	102.5
0.8	95.1	104.9	95.5	104.5 104.5	95.8	104.2	96.2	103.8	96.5	103.5	96.9	103.1	97.2	102.8	97.6	102.4
0.9 1.0	95.2 95.2	104.8 104.8	95.5 95.6	104.5	95.9 95.9	104.1 104.1	96.2 96.2	103.8 103.8	96.6 96.6	103.4 103.4	96.9 96.9	103.1 103.1	97.3 97.3	102.7 102.7	97.6 97.6	102.4 102.4
1.0	95.2	104.6	95.6 95.6	104.4	95.9	104.1	96.2	103.6	96.6	103.4	96.9	103.1	97.3	102.7	97.6	102.4
1.1	95.3	104.7	95.6 95.6	104.4	96.0	104.1	96.3	103.7	96.7	103.4	97.0	103.0	97.3 97.4	102.7	97.7	102.3
1.3	95.3 95.4	104.7	95.6	104.4	96.0	104.0	96.4	103.7	96.7	103.3	97.0	103.0	97.4	102.6	97.7	102.3
1.4	95.4	104.6	95.8	104.3	96.1	103.9	96.4	103.6	96.8	103.3	97.1	102.9	97.5	102.5	97.8	102.2
1.5	95.5	104.5	95.8	104.2	96.1	103.9	96.5	103.5	96.8	103.2	97.2	102.8	97.5	102.5	97.8	102.2
1.6	95.5	104.5	95.9	104.1	96.2	103.8	96.5	103.5	96.9	103.1	97.2	102.8	97.6	102.4	97.9	102.1
1.7	95.6	104.4	95.9	104.1	96.3	103.7	96.6	103.4	96.9	103.1	97.3	102.7	97.6	102.4	98.0	102.0
1.8	95.7	104.3	96.0	104.0	96.3	103.7	96.7	103.3	97.0	103.0	97.3	102.7	97.7	102.3	98.0	102.0
1.9	95.8	104.2	96.1	103.9	96.4	103.6	96.7	103.3	97.1	102.9	97.4	102.6	97.7	102.3	98.1	101.9
2.0	95.8	104.2	96.2	103.8	96.5	103.5	96.8	103.2	97.1	102.9	97.5	102.5	97.8	102.2	98.1	101.9
2.1	95.9	104.1	96.2	103.8	96.6	103.4	96.9	103.1	97.2	102.8	97.6	102.4	97.9	102.1	98.2	101.8
2.2	96.0	104.0	96.3	103.7	96.6	103.4	97.0	103.0	97.3	102.7	97.6	102.4	98.0	102.0	98.3	101.7
2.3	96.1	103.9	96.4	103.6	96.7	103.3	97.1	102.9	97.4	102.6	97.7	102.3	98.0	102.0	98.4	101.6
2.4	96.2	103.8	96.5	103.5	96.8	103.2	97.1	102.9	97.5	102.5	97.8	102.2	98.1	101.9	98.4	101.6
2.5	96.3	103.7	96.6	103.4	96.9	103.1	97.2	102.8	97.6	102.4	97.9	102.1	98.2	101.8	98.5	101.5
2.6	96.4	103.6	96.7	103.3	97.0	103.0	97.3	102.7	97.6	102.4	98.0	102.0	98.3	101.7	98.6	101.4
2.7	96.5	103.5	96.8	103.2	97.1	102.9	97.4	102.6	97.7	102.3	98.1	101.9	98.4	101.6	98.7	101.3
2.8	96.6	103.4	96.9	103.1	97.2	102.8	97.5	102.5	97.8	102.2	98.2	101.8	98.5	101.5	98.8	101.2
2.9	96.7	103.3	97.0	103.0	97.3	102.7	97.6	102.4	97.9	102.1	98.3	101.7	98.6	101.4	98.9	101.1
3.0	96.8	103.2	97.1	102.9	97.4	102.6	97.7	102.3	98.0	102.0	98.4	101.6	98.7	101.3	99.0	101.0
3.1	96.9	103.1	97.2	102.8	97.5	102.5	97.8	102.2	98.2	101.8	98.5	101.5	98.8	101.2	99.1	100.9
3.2	97.1	102.9	97.4	102.6	97.7	102.3	98.0	102.0	98.3	101.7	98.6	101.4	98.9	101.1	99.2	100.8
3.3	97.2	102.8	97.5	102.5	97.8	102.2	98.1	101.9	98.4	101.6	98.7	101.3	99.0	101.0	99.3	100.7
3.4	97.3	102.7	97.6	102.4	97.9	102.1	98.2	101.8	98.5	101.5	98.8	101.2	99.1	100.9	99.4	100.6
3.5	97.5	102.5	97.7	102.3	98.0	102.0	98.3	101.7	98.6	101.4	98.9	101.1	99.2	100.8	99.6	100.4
3.6	97.6	102.4	97.9	102.1	98.2	101.8	98.5	101.5	98.7	101.3	99.1	100.9	99.4	100.6	99.7	100.3
3.7	97.7	102.3	98.0	102.0	98.3	101.7	98.6	101.4	98.9	101.1	99.2	100.8	99.5	100.5	99.8	100.2
3.8 3.9	97.9 98.0	102.1 102.0	98.2	101.8	98.4 98.6	101.6 101.4	98.7	101.3 101.1	99.0 99.2	101.0 100.8	99.3 99.5	100.7	99.6	100.4	100.0	100.0
	98.0	102.0	98.3	101.7	98.7		98.9 99.0			100.8	99.5 99.6	100.5 100.4	99.8 100.0	100.2	•	•
4.0	98.3	101.6	98.4	101.6 101.4	98.9	101.3 101.1		101.0 100.8	99.3 99.5	100.7			100.0	100.0	•	•
4.1 4.2	98.5 98.5	101.7	98.6 98.7	101.4	98.9	101.1	99.2 99.3	100.8	99.5 99.6	100.5	99.8 100.0	100.2 100.0		•	•	•
4.2	98.5 98.6	101.5	98.7	101.3	99.0	101.0	99.3 99.5	100.7	99.6	100.4		100.0		•	•	•
4.3 4.4	98.8	101.4	98.9	101.1	99.2 99.3	100.8	99.5 99.6	100.5	100.0	100.2	•	•		•	•	•
4.5	99.0	101.2	99.2	100.9	99.5	100.7	99.8	100.4	100.0	100.0	•	•	•		•	•
4.6	99.2	100.8	99.4	100.6	99.7	100.3		100.2	•	•	•	•	•	•	•	•
4.7	99.3	100.7	99.6	100.4	99.9	100.3	•	•	•		•	•	•	•	•	•
4.8	99.5	100.7	99.8	100.4			•	•							•	•
4.9	99.8	100.2								•					•	•
5.0	100.0	100.0														



 TABLE 7
 Continued

	Standard Deviation of Location Means (%LC)														
SE (%LC)	4.1		4	4.2		.3	4.4		4.5		4.6				
	LL	UL	LL	UL	LL	UL	LL	UL	LL	UL	LL	UL			
0.1	97.8	102.2	98.2	101.8	98.5	101.5	98.9	101.1	99.2	100.8	99.6	100.4			
0.2	97.8	102.2	98.2	101.8	98.5	101.5	98.9	101.1	99.2	100.8	99.6	100.4			
0.3	97.8	102.2	98.2	101.8	98.5	101.5	98.9	101.1	99.2	100.8	99.6	100.4			
0.4	97.8	102.2	98.2	101.8	98.5	101.5	98.9	101.1	99.3	100.7	99.6	100.4			
0.5	97.9	102.1	98.2	101.8	98.6	101.4	98.9	101.1	99.3	100.7	99.6	100.4			
0.6	97.9	102.1	98.2	101.8	98.6	101.4	98.9	101.1	99.3	100.7	99.7	100.3			
0.7	97.9	102.1	98.2	101.8	98.6	101.4	99.0	101.0	99.3	100.7	99.7	100.3			
0.8	97.9	102.1	98.3	101.7	98.6	101.4	99.0	101.0	99.3	100.7	99.7	100.3			
0.9	97.9	102.1	98.3	101.7	98.6	101.4	99.0	101.0	99.4	100.6	99.7	100.3			
1.0	98.0	102.0	98.3	101.7	98.7	101.3	99.0	101.0	99.4	100.6	99.8	100.2			
1.1	98.0	102.0	98.4	101.6	98.7	101.3	99.1	100.9	99.4	100.6	99.8	100.2			
1.2	98.1	101.9	98.4	101.6	98.8	101.2	99.1	100.9	99.5	100.5	99.8	100.2			
1.3	98.1	101.9	98.4	101.6	98.8	101.2	99.1	100.9	99.5	100.5	99.9	100.1			
1.4	98.1	101.9	98.5	101.5	98.8	101.2	99.2	100.8	99.5	100.5	99.9	100.1			
1.5	98.2	101.8	98.5	101.5	98.9	101.1	99.2	100.8	99.6	100.4		-			
1.6	98.2	101.8	98.6	101.4	98.9	101.1	99.3	100.7	99.6	100.4					
1.7	98.3	101.7	98.6	101.4	99.0	101.0	99.3	100.7	99.7	100.3		-			
1.8	98.4	101.6	98.7	101.3	99.0	101.0	99.4	100.6	99.8	100.2		-			
1.9	98.4	101.6	98.8	101.2	99.1	100.9	99.5	100.5	99.8	100.2					
2.0	98.5	101.5	98.8	101.2	99.2	100.8	99.5	100.5	99.9	100.1		-			
2.1	98.6	101.4	98.9	101.1	99.2	100.8	99.6	100.4	100.0	100.0		-			
2.2	98.6	101.4	99.0	101.0	99.3	100.7	99.7	100.3	100.0	100.0		_			
2.3	98.7	101.3	99.0	101.0	99.4	100.6	99.7	100.3							
2.4	98.8	101.2	99.1	100.9	99.5	100.5	99.8	100.2				_			
2.5	98.9	101.1	99.2	100.8	99.5	100.5	99.9	100.1				_			
2.6	98.9	101.1	99.3	100.7	99.6	100.4	100.0	100.0				-			
2.7	99.0	101.0	99.4	100.6	99.7	100.3									
2.8	99.1	100.9	99.5	100.5	99.8	100.2									
2.9	99.2	100.8	99.6	100.4	99.9	100.1						_			
3.0	99.3	100.7	99.7	100.3	100.0	100.0									
3.1	99.4	100.6	99.8	100.2											
3.2	99.5	100.5	99.9	100.1						-					
3.3	99.7	100.3	100.0	100.0				-		-	-				
3.4	99.8	100.2													
3.5	99.9	100.1													

5.1.12 Example—A company wants to show with 90 % confidence, that a sample from a batch will have at least a 95 % probability of passing the USP UDU test. The sampling plan is to collect and test three dosage units from each of 20 approximately equally spaced locations throughout a batch. The results and summary statistics for each location are shown in Table 8.

5.1.12.1 The overall mean is 99.58 % label claim (%LC). The standard deviation of the 20 location means is 2.31 %LC and the within location standard deviation is 2.25 %LC. The acceptance limit table standard deviations are rounded to tenths. Therefore, to be conservative, the between and within location standard deviations are rounded up to 2.4 and 2.3, respectively. Using the Table 6 acceptance limits, the limits on

**TABLE 8 Content Uniformity Data/Summary Statistics** 

Location	1	2	3	Mean	Var	Std Dev
1	98.0	97.3	98.0	97.7	0.2	0.4
2	99.2	103.4	102.1	101.5	4.6	2.2
3	99.4	98.1	99.5	99.0	0.6	0.8
4	101.2	99.2	105.2	101.9	9.3	3.1
5	102.2	104.6	104.4	103.8	1.8	1.3
6	10.0	102.5	102.5	102.7	0.1	0.3
7	100.5	98.5	98.4	99.1	1.5	1.2
8	97.7	96.7	98.2	97.5	0.5	0.7
9	103.5	102.7	100.4	102.2	2.5	1.6
10	99.0	99.4	100.6	99.7	0.7	0.8
11	96.7	97.7	102.1	98.9	8.3	2.9
12	100.3	102.9	100.1	101.1	2.5	1.6
13	101.6	101.2	104.1	102.3	2.5	1.6
14	95.6	98.1	96.9	96.9	1.6	1.3
15	95.4	104.0	94.4	97.9	28.0	5.3
16	100.2	96.4	98.3	98.3	3.6	1.9
17	102.2	94.6	101.9	99.6	18.5	4.3
18	101.1	98.5	97.9	99.2	2.8	1.7
19	100.1	95.0	98.0	97.7	6.5	2.5
20	97.0	92.7	94.1	94.6	4.7	2.2



the overall sample mean are 94.6 % to 105.4 %LC. Since 99.58 falls between these limits on the overall mean, the sample passes the acceptance criteria. Therefore, with 90 % confidence, there is at least a 95 % probability that the batch would pass the USP UDU <905> test.

# 5.2 Selection of Sample Size:

5.2.1 To select the size of sample to be taken, the probability that sample statistics ( $\bar{X}$ , s) will lie within acceptance limits should be evaluated over a range of sample sizes for selected values of population parameters ( $\mu$ ,  $\sigma$ ) of practical interest (for example, based on product history or development lots). For

selected values of the population parameters, the probability of passing the UDU test should be higher than the lower bound. The probability of passing the acceptance limit depends on the sample size. The larger the sample size n that is chosen, the larger will be the acceptance region and the tighter the distribution of the statistics. For expected values of the population parameters, choose n so that the probability of passing acceptance limits is greater than a desired value.

# 6. Keywords

6.1 acceptance limits; acceptance sampling inspection; multiple-stage sampling test; uniformity of dosage units

### REFERENCES

- (1) Bergum, J. S., "Constructing Acceptance Limits for Multiple Stage Tests," *Drug Development and Industrial Pharmacy*, Vol 16, No. 14, 1990, pp. 2153–2166.
- (2) Bergum, J. S., and Utter, M. L., "Process Validation," *Encyclopedia of Bio-pharmaceutical Statistics*, Marcel Dekker: New York, NY, 2000, pp. 422–439.
- (3) Bergum, J. S., and Utter, M. L., "Statistical Methods for Uniformity and Dissolution Testing," *Pharmaceutical Process Validation*, 3rd ed., edited by R. A. Nash and A. H. Watchter, Marcel Dekker: New York, NY, 2003, pp. 667–697.
- (4) Bergum, J. S., and Li, H., "Acceptance Limits for the New ICH USP 29 Content Uniformity Test," *Pharmaceutical Technology*, October 2007, pp. 90–100.
- (5) Lindgren, B. W., Statistical Theory, Macmillan, New York, NY, 1968.
- (6) ICH Q4B Annex 6(R1), "Evaluation and Recommendation of Phar-

- macopoeial Texts for Use in the ICH Regions on Uniformity of Dosage Units General Chapter," *International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use*, September 27, 2010.
- (7) Garcia, T., Bergum, J., Prescott, J., Tejwani, R., Parks, T., Clark, J., Brown, W., Muzzio, F., Patel, S., and Hoiberg, C, "Recommendations for the Assessment of Blend and Content Uniformity: Modifications to Withdrawn FDA Draft Stratified Sampling Guidance," *Journal of Pharmaceutical Innovation*, Vol 10, 2015, pp. 76–83.
- (8) Bergum, J., Prescott, J., Tejwani, R., Parks, T., Clark, J., Brown, W., Muzzio, F., Patel, S., and Hoiberg, C., "Assessment of Blend and Content Uniformity. Technical Discussion of Sampling Plans and Application of ASTM E2709/E2810," *Journal of Pharmaceutical Innovation*, Vol 10, 2015, pp. 84–97.

ASTM International takes no position respecting the validity of any patent rights asserted in connection with any item mentioned in this standard. Users of this standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, are entirely their own responsibility.

This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, at the address shown below.

This standard is copyrighted by ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959, United States. Individual reprints (single or multiple copies) of this standard may be obtained by contacting ASTM at the above address or at 610-832-9585 (phone), 610-832-9555 (fax), or service@astm.org (e-mail); or through the ASTM website (www.astm.org). Permission rights to photocopy the standard may also be secured from the Copyright Clearance Center, 222 Rosewood Drive, Danvers, MA 01923, Tel: (978) 646-2600; http://www.copyright.com/