Sampling Guidelines for Bulk Materials and Multi-Unit Populations

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1 INTRODUCTION

This procedure describes statistical and non-statistical sampling approaches for General Chemistry items consisting of bulk material or multi-unit populations. Due to the nature of the cases and items that General Chemistry analyzes, no one approach is sufficient. For all item types, additional samples may be examined as deemed necessary. For example, a product tampering case may necessitate the analysis of all units within a population.

2 SCOPE

This procedure applies to Chemistry Unit (CU) personnel that are qualified to examine General Chemistry evidence.

3 SAMPLING

3.1 Bulk Materials

3.1.1 Homogeneous

A single, representative sample may be selected for analysis from a bulk material that is visually homogeneous (e.g., single layer liquids, solids with evenly distributed components).

3.1.2 Heterogeneous

A single, representative sample may be selected for analysis from a bulk material that is visually heterogeneous. The *Laboratory Report* shall clearly limit the results of examinations to the sample that was examined.

If the results of examinations are to be applied to the entirety of the item, then the material will be homogenized prior to analysis. This may be accomplished by sampling multiple, representative areas of the item and homogenizing with a mortar and pestle. Alternatively, the sample may be broken down into multiple, homogeneous samples prior to analysis (e.g., particle picking). The details of the sampling approach will be recorded in the case notes and the *Laboratory Report* will clearly communicate any limitations.

3.2 Multi-Unit Populations

An item can be treated as a multi-unit population if it consists of 2 or more units that have similar physical properties (e.g., color, shape, size, logos, markings, imprints).

3.2.1 Non-Statistical Sampling

One or more units may be randomly selected for analysis. When non-statistical sampling is utilized, the *Laboratory Report* shall clearly limit the results of examinations to the units that were examined.

3.2.2 Statistical Sampling

As appropriate, the contributor will be contacted to determine if an inference is necessary, or if non-statistical sampling is sufficient. The details of this conversation will be recorded on the applicable Communication Log. If an inference is to be made about the population, then statistical sampling will be performed. See Appendix A to determine the number of units to randomly select for analysis (without replacement). The Hypergeometric Table utilizes a 95% confidence interval for an inference about 90% of the population. Adjustments to the table will be necessary if the confidence interval and/or population % are changed. Additionally, Appendix A assumes that all results are consistent. If inconsistent results are encountered, additional units may need to be analyzed and/or adjustments to the inference values may be required (see Appendix B).

4 CALCULATIONS

Following is an example inference made utilizing statistical sampling of a population. See Appendices A and B for further details.

> *Item 1 consisted of 263 small, round, light blue tablets with "M" and "30" imprints (indicative of 30 milligram oxycodone hydrochloride tablets). Per the Hypergeometric Table (Appendix A), 27 tablets were randomly selected and sub-itemized (Items 1-1 through 1-27). Oxycodone was identified within each of the Item 1-1 through 1-27 tablets.*
>
> *A combination of the results of examinations and the sampling plan utilized allows for the inference that ≥ 236 of the 263 submitted tablets would be expected to contain oxycodone. This inference is made at a 95% confidence level.*

5 LIMITATIONS

When non-statistical sampling is used, the *Laboratory Report* will clearly state that the results are limited to the sample(s) or portion(s) of sample(s) that was analyzed.

If inconsistent results are obtained during the analysis of the samples selected under section 3.2.2, then the proportion of the population will be adjusted to maintain a 95% confidence level for an inference about the population. An example calculation can be found in Appendix B.

6 REVISION HISTORY

Revision	Issue Date	Changes
05	05/06/2022	Revised to match new format requirements. No substantive changes to content.
06	09/01/2022	Revised Hypergeometric Table; changeover from 28 to 29 samples was a population size ≥ 1601 in Revision 05.

APPENDIX A: HYPERGEOMETRIC TABLE

The hypergeometric table listed below shows the minimum number of samples that need to be analyzed (and yield consistent results) to obtain a 95% confidence level that at least 90% of the population contains a given substance.

Total Number of Units	Number of Units to be Sampled
1-10	All (no inferences)
11-13	10
14	11
15-16	12
17	13
18	14
19-24	15
25-26	16
27	17
28-35	18
36-37	19
38-46	20
47-48	21
49-58	22
59-77	23
78-88	24
89-118	25
119-178	26
179-298	27
299-1008	28
≥ 1009	29

APPENDIX B: EXAMPLE FOR ESTIMATING PROPORTION OF POPULATION

Following is an example of how to estimate the proportion of the population that contains a substance for the situation where 1 or more randomly selected samples provided negative or inconsistent results:

A submission to the laboratory consisted of 125 physically similar tablets (no manufacturer's logos). Per the table in Appendix A, 26 samples were randomly selected and analyzed. MDMA was identified in 25 of the samples, while no controlled substances were identified within 1 of the samples. The "NUMBER OF SUCCESSES IN THE SAMPLE", "SAMPLE SIZE", and "POPULATION SIZE" cells were entered in the below table (25, 26, 125, respectively). The entry in the "NUMBER OF SUCCESSES IN THE POPULATION" cell was then varied until the "% CONFIDENCE LEVEL" cell became just ≥ 95%. At that point, take note of the value in the "% POPULATION THAT CONTAINS SUBSTANCE" cell. This is the new value that would replace the value "90%" for the situation where all samples selected were consistent when analyzed. For this example, the report would read to the effect "at a 95% confidence level, it is estimated that at least 106 tablets contained MDMA".

NUMBER OF SUCCESSES IN THE SAMPLE (X)	25
SAMPLE SIZE (n)	26
INFERRED NUMBER OF SUCCESSES IN THE POPULATION*** (R)	106
POPULATION SIZE (N)	125
PROB. of X successes for above n, R, N *** VARY THIS VALUE SUCH THAT % CONF. LEVEL ≥ 95%	0.048421
% CONFIDENCE LEVEL	**95.2**
INFERRED % POPULATION THAT CONTAINS SUBSTANCE	**84.8**