Introduction

The Nutrient Data Laboratory (NDL) at the U.S. Department of Agriculture is collaborating with the Office of Dietary Supplements at the National Institutes of Health, the National Center for Health Statistics at the Centers for Disease Control and Prevention, and the Nutrient Institute at Standards and Technology (NIST) to develop the Dietary Supplement Ingredient Database (DSID), an analytically supported database of dietary supplement ingredient information. With the high prevalence of dietary supplement use in the U.S., evaluating the levels of nutrients provided by these products has become vital for assessing total intake. The primary use of this database will be to support research estimating the intakes of nutrients from supplements and food in the U.S.

The goals for the DSID are to:
- (a) develop reliable estimates of ingredients in dietary supplements (DSs),
- (b) assess variability and possible overages when computing analytic nutrient levels in labeled levels,
- (c) release and maintain a publicly available on-line dietary supplement composition database.

Multivitamin/mineral (MVM) products were chosen for the initial studies because these dietary supplements were the most commonly reported dietary supplements in the 2001-02 National Health and Nutrition Examination Survey (NHANES). Thirty-five percent of U.S. adults who participated in 2001-02 NHANES reported taking a MVM within the past month.

Results and Discussion

Objectives

1) To determine the variability of folic acid, vitamin C, folic acid, and vitamin E content within product lots.

2) To determine the variability of folic acid, vitamin C, folic acid, and vitamin E content between product lots.

Methods and Materials

MVM adult products (n=56) reported in NHANES 2001-02 were identified and tablets were summarized to determine label levels of iron, ascorbic acid, α-tocopherol, and folic acid. Three %DV percent Daily Values) levels for each nutrient were chosen for study based on the following factors: weighted frequency of use, range of %DV levels, and number of supplements reported for each %DV level. Figure 1 shows the study plan including %DV levels and within-lot sample size for each nutrient. Seven MVM products were randomly chosen for analysis to represent each of the three %DV levels for a total of 21 products per nutrient. Two lots of each product were purchased locally for sampling.

Within-lot sample size was estimated for each nutrient based on preliminary USDA data on within-lot variability in order to detect a 18% difference between lots with a 95% confidence (iron, n=2; ascorbic acid and folic acid, n=3; α-tocopherol, n=4). Twenty tablets of each sample plus 20 tablets of 2 control materials per nutrient were used in 3 different batches on different days to an independent laboratory. The test “tablet(s)”, will be used to denote a unit or units that may be tablets, capsules, capsules, caps or softgels. Twenty tablets of each sample were homogenized on the same day as analysis. Methods of analysis are listed in Table 1.

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Method of Analysis</th>
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</thead>
<tbody>
<tr>
<td>Iron</td>
<td>Inductively Coupled Plasma-Atomic Emission Spectrometry (ICP)</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>High Performance Liquid Chromatography (HPLC)</td>
</tr>
<tr>
<td>α-Tocopherol</td>
<td>High Performance Liquid Chromatography (HPLC)</td>
</tr>
<tr>
<td>Folic Acid</td>
<td>HPLC</td>
</tr>
</tbody>
</table>

Table 1: Methods of Analysis

Mean, standard deviation (SD), and coefficient of variation (%CV) were estimated from data expressed as mg/serving for folic acid. ANOVA was used to determine lot-to-lot variance.

Conclusions

- 1) 2 lots per product are needed to detect between-lot variability that is in addition to within-lot variability seen in this study. Further study of between-lot variability, using 4 lots per product, is in progress at NDE.
- Acceptable laboratory variability for folic acid values may be higher than the 10% seen with other nutrient analyses for multi-vitamin/multi-mineral supplement products due to the microbiological method required.
- Preliminary data from this project and other dietary supplement ingredient projects at NDE, will be used to populate the DSID.

References

3) www.nd.gov/usda

Figures:

- Figure 1: Study plan
- Figure 2: Within-lot Analytical Mean ± SD for Iron Levels in 9 MVM Products, 2 Replicates Per Lot
- Figure 3: Within-lot Analytical Mean ± SD for Ascorbic Acid Levels in 9 MVM Products, 3 Replicates Per Lot
- Figure 4: Within-lot Analytical Mean ± SD for α-Tocopherol Levels in 9 MVM Products, 3 Replicates Per Lot
- Figure 5: Within-lot Analytical Mean ± SD Folic Acid Levels in 9 MVM Products, 3 Replicates Per Lot