AOAC SMPR® 2011.010

Standard Method Performance Requirement for Vitamin E in Infant Formula and Adult/Pediatric Nutritional Formula

Intended Use: Global Dispute Resolution Method

1 Applicability

Determination of vitamin E in all forms of infant, adult, and/or pediatric formula, with a focus on D-alpha-tocopherol (CAS 59-02-9) and *all*-racemic alpha-tocopherol (CAS 1406-18-4), and their esters. Methods must be able to report the quantity of alpha-tocopherol and esters separately.

2 Analytical Technique

Any analytical technique that meets the following method performance requirements is acceptable.

3 Definitions

Adult/pediatric formula.—Nutritionally complete, specially formulated food, consumed in liquid form, which may constitute the sole source of nourishment (AOAC SPIFAN, 2010), made from any combination of milk, soy, rice, whey, hydrolyzed protein, starch, and amino acids, with and without intact protein.

Infant formula.—Breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding (Codex Standard 72-1981), made from any combination of milk, soy, rice, whey, hydrolyzed protein, starch, and amino acids, with and without intact protein.

Limit of detection (LOD).—The minimum concentration or mass of analyte that can be detected in a given matrix with no greater than 5% false-positive risk and 5% false negative risk.

Limit of quantitation (LOQ).—The minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.

Repeatability.—Variation arising when all efforts are made to keep conditions constant by using the same instrument and operator, and repeating during a short time period. Expressed as the repeatability standard deviation (SD_r); or % repeatability relative standard deviation (%RSD_r).

Reproducibility.—The SD or RSD calculated from among-laboratory data. Expressed as the reproducibility standard deviation (SD_R); or % reproducibility relative standard deviation (%RSD_R).

Recovery.—The fraction or percentage of spiked analyte that is recovered when the test sample is analyzed using the entire method.

4 Method Performance Requirements

See Table 1.

Table 1. Method performance requirements[a]

Analytical range	0.2–8[b]	
Limit of detection (LOD)	≤0.1[b]	
Limit of quantitation (LOQ)	≤0.2[b]	
Repeatability (RSD_r)	≤2.0[b]	≤8%
	>2[b]	≤6%
Recovery	90–110% of mean spiked recovery over the range of the assay	
Reproducibility (RSD_R)	≤0.5[b]	≤22%
	>0.5[b]	≤16%

[a] Concentrations apply to: (*1*) "ready-to-feed" liquids, "as is"; (*2*) reconstituted powders (25 g into 200 g water); and (*3*) liquid concentrates diluted 1:1 by weight.

[b] mg/100 g α-tocopherol and α-tocopheryl acetate in reconstituted final product.

5 System Suitability Tests and/or Analytical Quality Control

Suitable methods will include blank check samples and check standards at the lowest point and midrange point of the analytical range.

6 Reference Method(s)

AOAC *Official Methods of Analysis*℠ **992.03** (*see* 50.1.04), Vitamin E Activity (*all-rac*-alpha-Tocopherol) in Milk-Based Infant Formula may be used with the following caveat: OMA **992.03** (*see* 50.1.04) has been validated for milk-based formula only.

7 Reference Material(s)

NIST Standard Reference Material® 1849 Infant/Adult Nutritional Formula, or equivalent. The SRM is a milk-based, hybrid infant/adult nutritional powder prepared by a manufacturer of infant formula and adult nutritional products. A unit of SRM 1849 consists of 10 packets, each containing approximately 10 g material. NIST 1849 assigned the following values for vitamin E vitamers: 369 ± 16 mg/kg alpha-tocopherol; 189 ± 13 mg/kg gamma-tocopherol; 79 ± 2.4 mg/kg delta-tocopherol; and 5.77 ± 0.79 mg/kg beta-tocopherol.

8 Validation Guidance

Recommended level of validation: *Official Methods of Analysis*℠.

9 Maximum Time-to-Signal

No maximum time.

Approved by Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN). Final Version Date: October 4, 2011. Effective Date: September 17, 2011.