AOAC SMPR® 2012.012

Standard Method Performance Requirements for Vitamin C in Infant Formula and Adult/Pediatric Nutritional Formula

Intended Use: Global dispute resolution method

1 Applicability

Determination of vitamin C in all forms of infant, adult, or pediatric formula (powders, ready-to-feed liquids, and liquid concentrates). For the purpose of this SMPR, vitamin C is defined as the sum of L-ascorbic acid or its salts, and de-hydro ascorbic acid.

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 made from combination of milk, soy, rice, whey, hydrolyzed protein, hydrolyzed lactose, 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, made from 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.

Reproducibility.—The standard deviation or relative standard deviation calculated from among-laboratory data, expressed as reproducibility relative standard deviation or % reproducibility relative standard deviation.

Table 1. Method performance requirements[a,b]

Analytical range	1.0–250 mg/100 g	
Limit of detection (LOD)	0.3 mg	
Limit of quantitation (LOQ)	1.0 mg	
Repeatability (RSD_r)	1.0–10 mg	≤10%
	>10 mg	≤5%
Recovery	90 to 110% of mean spiked recovery over the range of the assay	
Reproducibility (RSD_R)	1.0–10 mg	≤15%
	>10 mg	≤10%

[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] For all concentrations, vitamin C will be expressed as mg/100 g reconstituted liquids.

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.

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 Material(s)

NIST Standard Reference Material® (SRM) 1849a Infant/Adult Nutritional Formula, or equivalent. The SRM is milk-based, hybrid infant/adult nutritional powder prepared by a manufacturer of infant formula. The certified NIST value for SRM 1849a is 784 ± 65 mg/kg as ascorbic acid.

7 Validation Guidance

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

8 Maximum Time-to-Result

No maximum time.

Approved by the AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) on September 29, 2012. Final Version Date: September 29, 2012.