AOAC SMPR® 2021.002

Standard Method Performance Requirements (SMPRs®) for Determination of Vitamin C (L-Ascorbic Acid) in All Forms of Infant Formula, Follow-Up Formula, Baby Food, Adult/Pediatric Formula, Complementary Food Supplements, Nutritional Supplements for Pregnant Women and Nursing Mothers, and Sports Nutrition Food

Intended Use: Reference Method for Dispute Resolution

1 Purpose

AOAC SMPRs describe the minimum recommended performance characteristics to be used during the evaluation of a method. The evaluation may be an on-site verification, a single-laboratory validation, or a multi-site collaborative study. SMPRs are drafted by AOAC working groups composed of representatives from industry, regulatory organizations, contract laboratories, test kit manufacturers, and academic institutions. Approved by AOAC, AOAC SMPRs may be used for method development, are used by AOAC expert review panels in their evaluation of validation study data for methods being considered for AOAC *Performance Tested Methods*℠ or AOAC *Official Methods of Analysis*℠ and can be used as acceptance criteria for verification at user laboratories.

2 Applicability

Determination of vitamin C (L-ascorbic acid) in all forms of infant formula, follow-up formula, baby food, adult/pediatric formula, complementary food supplements, nutritional supplements for pregnant women and nursing mothers, and sports nutrition food. For the purpose of this SMPR, vitamin C is defined as the sum of L-ascorbic acid or its salts, and dehydro ascorbic acid. Reported as vitamin C (L-ascorbic acid).

For the purpose of this SMPR, D-ascorbic acid (erythorbic acid) and ascorbyl palmitate are excluded from the definition of vitamin C.

3 Analytical Technique

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

4 Definitions

Accuracy.—Closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value (corresponds to the VIM definition for "trunesstrueness").

Adult/pediatric formula.—Formula for special medical purposes for infants or adults. A nutritionally complete, specially formulated food, consumed in liquid form, which may constitute the sole source of nourishment, made from any combination of milk, soy, rice, whey, hydrolyzed protein, starch, and amino acids, with and without intact protein. Excluding infant formula, follow-on formula and baby food.

Baby food.—Intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation, to ordinary food, including processed cereal-based food and canned complementary foods.

Complementary food supplement.—A supplement containing a variety of micronutrients (vitamins and minerals, etc.), which contains or does not contain food matrix and other auxiliary materials. It is added to the instant food supplement for infants and young children aged 6 to 36 months. It can also be used for 37 months–60-month-old child. It can be formulated as powder, tablets or spraying agent.

Follow-up infant formula.—Food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children.

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.

Limit of detection (LOD).—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).—Minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.

Nutritional supplements for pregnant women and nursing mothers.—Special dietary foods made with high-quality protein and a variety of micronutrients (minerals, vitamins, etc.) suitable for pregnant women and lactating mothers to supplement nutrients.

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

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

Sports nutrition food.—Specially processed foods for special needs. Formulated to meet the physiological metabolic status, exercise capacity and certain nutritional components of the sports crowd (referring to people who participate in physical exercise 3 times or more per week, each duration of 30 mins or more, and each exercise intensity of medium or above).

Vitamin C (ascorbic acid).—L-ascorbic acid, with the exception of D-ascorbic acid (erythorbic acid).

5 Method Performance Requirements

See Table 1.

6 System Suitability Tests and/or Analytical Quality Control

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

7 Reference Material(s)

NIST Standard Reference Material® (SRM) 1869 Infant/Adult Nutritional Formula II, or equivalent. The SRM is a soy, whey, and milk protein concentrate-based, hybrid infant/adult nutritional powder, prepared by a manufacturer of infant formula and adult nutritional products. The certified NIST value for SRM 1869 is 897 ± 43 mg/kg as ascorbic acid.

8 Validation Guidance

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

9 Maximum Time-to-Result

No maximum time.

Developed by AOAC Stakeholder Program on Infant Formula and Adult Nutritionals (SPIFAN) Working Group on Collaboration on Vitamin C in Regional Matrices (Collaboration with AOAC China Section). Approved by SPIFAN on April 30, 2021. Final Version Date: April 30, 2021 (version 3)

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Table 1. Method performance requirements[a,b]

Analytical range	1–250 mg/100 g
Limit of quantitation (LOQ)	1.0 mg/100 g
Recovery	90–110% of mean spiked recovery
Repeatability (RSD_r)	1–10 mg/100 g ≤10% > 10 mg/100 g ≤5%
Reproducibility (RSD_R)	1–10 mg/100 g ≤15% > 10 mg/100 g ≤10%

[a] Concentrations apply to products as consumed: For infant and follow-on formulas: (*1*) 'ready-to-feed" liquids "as is"; (*2*) reconstituted powders (25 g into 200 g water); (*3*) liquid concentrates diluted 1:1 by weight. For other products depending on specific instructions for preparation.

[b] For all concentrations, vitamin C is expressed as mg/100 g of products as consumed.