AOAC SMPR® 2011.008

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

Intended Use: Global Dispute Resolution Method

1 Applicability

Determination of nucleotides in all forms of infant, adult, and/or pediatric formula (powders, ready-to-feed liquids, and liquid concentrates). For the purpose of this SMPR, nucleotides are defined as adenosine 5′-monophosphate (CAS 61-19-8), cytidine 5′-monophosphate (CAS 63-37-6), guanosine 5′-monophosphate (CAS 85-32-5), inosine 5′-monophosphate (CAS 131-99-7), and uridine 5′-monophosphate (CAS 58-97-9). It would also be desirable to measure the corresponding nucleosides: adenosine (CAS 58-61-7), cytidine (CAS 65-46-3), guanosine (CAS 118-00-3), inosine (CAS 58-63-9), and uridine (CAS 58-96-8).

2 Analytical Technique

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

3 Definitions

*Adult/pediatric formul*a.—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.

Table 1. Method performance requirements[a]

Analytical range	0.02–3.5[b]	
	0.31–22.3[c]	
Limit of detection (LOD)	≤0.006[b]	
Limit of quantitation (LOQ)	≤0.02[b]	
Repeatability (RSD_r)	≤0.02[b]	≤10%
	0.02–1[b]	≤8%
	>1[b]	≤6%
Recovery	90–110% of mean spiked recovery over the range of the assay	
Reproducibility (RSD_R)	≤0.02[b]	≤20%
	0.02–1[b]	≤16%
	>1[b]	≤11%

[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 individual nucleotide results reported.

[c] mg/100 g aggregate of all five nucleotide results reported.

4 Method Performance Requirements

See Table 1.

5 System Suitability Tests and/or Analytical Quality Control

Suitable methods will include blanks and quality control check samples.

6 Reference Material(s)

National Institute of Standards and Technology (NIST) Standard Reference Material (SRM) 1849 Infant/Adult Nutritional Formula. 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 of material. Reference values are given as 106 (±5) mg/kg for adenosine 5′-monophosphate; 305 (±5) mg/kg for cytidine 5′-monophosphate; 147 (±38) mg/kg for guanosine 5′-monophosphate; and 148 (±8) mg/kg for uridine 5′-monophosphate.

7 Validation Guidance

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

8 Maximum Time-to-Signal

No maximum time.

Approved by Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN). Final Version Date: September 17, 2011. Effective Date: September 20, 2011.