AOAC SMPR 2014.002

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

Intended Use: Reference Method for Dispute Resolution

1 Applicability

Determination of fructans in all forms of infant, adult, and/or pediatric formula (powders, ready-to-feed liquids, and liquid concentrates).

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 Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN); 2010], made from any combination of milk, soy, rice, whey, hydrolyzed protein, starch, and amino acids, with and without intact protein.

Fructans.—Fructans including oligofructose, fructooligosaccharides, and inulin. General formulae are shown in Figure 1.

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.

GF_n Type: (ß-D-Fru*f*-(2→1))$_n$-ß-D-Fru*f*-(2↔1)-α-D-Glc*p*

F_m Type: (ß-D-Fru*f*-(2→1))$_n$-(2 →1)-D-Fru*f*

where n≥1

Figure 1. General formulae for the two major inulin-type fructans. GF_n type do not have a reducing end and contain a terminal glucose, F_m type have a reducing end and do not have a terminal glucose. Fru*f* = fructofuranose; Glc*p* = glucopyranose.

Table 1. Method performance requirements[a]	
Analytical range	0.03–5.0[b]
Limit of quantitation (LOQ)	≤0.03[b]
Repeatability (RSD_r)	≤6%
Recovery	90 to 110% of mean spiked recovery over the range of the assay
Reproducibility (RSD_R)	≤12%
[a] Concentrations apply to (a) "ready-to-feed" liquids "as is"; (b) reconstituted powders (25 g into 200 g of water); and (c) liquid concentrates diluted 1:1 by weight.	
[b] g/100 g reconstituted final product.	

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 standard deviation or relative standard deviation calculated from among-laboratory data. Expressed as the reproducibility relative 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.

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)

No National Institute of Standards and Technology (NIST) Standard Reference Material® (SRM) 1849a Infant/Adult Nutritional Formula or equivalent is available.

7 Validation Guidance

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

8 Maximum Time-to-Result

No maximum time.

Approved by AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN). Final Version Date: March 18, 2014.