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 Nutritional (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.

**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); or % repeatability relative standard deviation (%RSD).

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

**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℠.

8 Maximum Time-to-Result

No maximum time.

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

<table>
<thead>
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<th>Table 1. Method performance requirements*</th>
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<tr>
<td>Analytical range</td>
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<td>Limit of quantitation (LOQ)</td>
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<td>Repeatability (RSD)&lt;sub&gt;r&lt;/sub&gt;</td>
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<td>Recovery</td>
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<td>Reproducibility (RSD)&lt;sub&gt;R&lt;/sub&gt;</td>
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<sup>a</sup> 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.

<sup>b</sup> g/100 g reconstituted final product.

**Figure 1.** General formulae for the two major inulin-type fructans. GF<sub>n</sub> type do not have a reducing end and contain a terminal glucose, Fm type have a reducing end and do not have a terminal glucose. Fru = fructofuranose; Glcp = glucopyranose.