

## Standard Method Performance Requirements (SMPR®) for GOS in Infant Formula and Adult/Pediatric Nutritional Formula

Intended Use: Reference Method for Dispute Resolution

### 1 Applicability

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

### 2 Analytical Technique

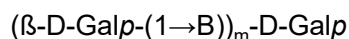
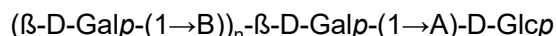
Any analytical technique that meets the following method performance requirements is acceptable.

### 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.

*Galactooligosaccharides (GOS).*—Also known as oligogalactosyllactose, oligogalactose, or transgalactooligosaccharides (TOS) produced by transgalactosylation of lactose. 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.



where  $n \geq 0$ ;  $m \geq 1$

$B = 2, 3, 4, \text{ or } 6$

If  $n > 0$ ,  $A = 1, 2, 3, 4, \text{ or } 6$

If  $n = 0$ ,  $A = 1, 2, 3 \text{ or } 6$

**Figure 1. General formulae for galactooligosaccharides, which may or may not contain a terminal glucose. Although not obvious from this generalized scheme, branched structures may also exist. Galp = galactopyranose; Glcp = glucopyranose.**

Analytical range	0.2–3.0 <sup>b</sup>
Limit of quantitation (LOQ)	≤0.2 <sup>b</sup>
Repeatability (RSD <sub>r</sub> )	≤6%
Recovery	90 to 110% of mean spiked recovery over the range of the assay
Reproducibility (RSD <sub>R</sub> )	≤12%
<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.	

*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.

*Recovery.*—The fraction or percentage of spiked analyte that is recovered when the test sample is analyzed using the 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<sub>r</sub>); or % repeatability relative standard deviation (%RSD<sub>r</sub>).

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

### 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*<sup>SM</sup>.

### 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. Revised: March 2018.