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 Nutritional (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.

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 AnalysisSM.

8 Maximum Time-to-Result
No maximum time.


Table 1. Method performance requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Requirement Value</th>
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<tbody>
<tr>
<td>Analytical range</td>
<td>0.2–3.0g</td>
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<tr>
<td>Limit of quantitation (LOQ)</td>
<td>≤0.2g</td>
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<tr>
<td>Repeatability (RSDr)</td>
<td>≤6%</td>
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<td>Recovery</td>
<td>90 to 110%</td>
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<tr>
<td>Reproducibility (RSDR)</td>
<td>≤12%</td>
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* 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.

** 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.**

\[(\beta-D-Galp-(1\rightarrow B))_n-\beta-D-Galp-(1\rightarrow A)-D-Glcp\]

\[(\beta-D-Galp-(1\rightarrow B))_m-D-Galp\]

where n ≥ 0; m ≥ 1
B = 2, 3, 4, or 6
If n > 0, A = 1, 2, 3, 4, or 6
If n = 0, A = 1, 2, 3, 6