## AOAC SMPR® 2012.010

## *Standard Method Performance Requirements* for L-Carnitine in Infant Formula and Adult/Pediatric Nutritional Formula

Intended Use: Global dispute resolution method

### *1 Applicability*

Determination of supplemented and endogenous L-carnitine [3-hydroxy-4-(trimethylazaniumyl) butanoate; CAS No. 541-15-1] in all forms of infant, adult, and/or pediatric formula (powders, ready-to-feed liquids, and liquid concentrates). Methods must be able to determine free and total carnitine; report as L-carnitine.

### *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.

*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 (%$RSD_r$).

**Table 1. Method performance requirements**[a]

| | |
|---|---|
| Analytical range | 0.16–20[b] |
| Limit of quantitation (LOQ) | ≤0.16[b] |
| Repeatability ($RSD_r$) | ≤8% |
| Recovery | 90 to 110% of mean spiked recovery over the range of the assay |
| Reproducibility ($RSD_R$) | ≤15% |

[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 reconstituted final product.

*Reproducibility*.—The standard deviation or relative standard deviation 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.

### *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)*

NIST Standard Reference Material® (SRM) 1849a Infant/Adult Nutritional Formula, or equivalent. 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 1849a consists of 10 packets, each containing approximately 10 g material. Certified value of NIST 1849a is 136 mg/kg L-carnitine.

### *7 Validation Guidance*

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

### *8 Maximum Time-to-Result*

Less than 24 h.

*Approved by the AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) on September 29, 2012. Final Version Date: September 29, 2012.*