

Standard Method Performance Requirements for Whey Protein:Casein Ratio in Infant Formula

Intended Use: Global dispute resolution method

1 Applicability

Determination of total whey proteins, including hydrolyzed forms, as a percent of protein content (protein content as defined by appropriate regulatory agencies). To be applicable to milk-based infant formula products (including those from bovine milk and, if possible, milk of other species and products containing hydrolyzed casein).

2 Analytical Technique

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

3 Definitions

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, whey, hydrolyzed milk protein, starch, and amino acids, with and without intact protein.

Whey protein.—For the purpose of this SMPR, whey protein is defined as the proteinaceous components obtained from milk after removal of casein components by various processing technologies.

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

Analytical range	20–100 ^a	
Limit of quantitation (LOQ)	≤10 ^a	
Repeatability (RSD _r)	20–100 ^a	≤3%
Recovery	95 to 105% of theoretical	
Reproducibility (RSD _R)	20–100 ^a	≤6%
^a g/100 g protein (unless otherwise specified in regulation).		

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 standard deviation (SD_R); or % reproducibility relative standard deviation (%RSD_R).

Recovery.—The fraction or percentage of analyte that is recovered versus a known amount in a test sample when 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 check standards at the lowest point and midrange point of the analytical range.

6 Reference Material(s)

To be determined.

7 Validation Guidance

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

8 Maximum Time-to-Result

No maximum time.

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