AOAC SMPR 2018.009

Standard Method Performance Requirements (SMPRs®) for Lactose in Low-Lactose or Lactose-Free Milk, Milk Products, and Products Containing Dairy Ingredients

Intended Use: Method for Confirming Compliance with Regulatory Standards and Dispute Resolution

1 Purpose

AOAC SMPRs describe the minimum recommended performance characteristics to be used during the evaluation of a method. The evaluation may be an on-site verification, a single-laboratory validation, or a multi-site collaborative study. SMPRs are written and adopted by AOAC stakeholder panels composed of representatives from the industry, regulatory organizations, contract laboratories, test kit manufacturers, and academic institutions. AOAC SMPRs are used by AOAC expert review panels in their evaluation of validation study data for method being considered for *Performance Tested Methods*℠ or AOAC *Official Methods of Analysis*℠, and can be used as acceptance criteria for verification at user laboratories.

2 Applicability

Measure lactose found in milk, milk products, and products containing dairy ingredients that are low-lactose or lactose-free. The analytical method must account for potential interferences (*see* Table 1) in these matrices. This scope includes "lactose-free" infant formulas and adult nutritionals.

3 Analytical Technique

Any analytical technique(s) that measures the analyte(s) of interest and meets the following method performance requirements is/are acceptable.

4 Definitions

Infant formula.—Breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infant during the first months of life up to the introduction of appropriate complementary feeding (Codex Standard 72-1981) Infant Formula and Formulas for Special Medical Purposes – 0–12 month of age; Follow-Up Formula – from 6–12 months and for young children; Young Children – 12–36 months of age; Foods for Special Medical Purposes Nutritionally complete specially formulated food for adults, consumed in liquid form, which may constitute the sole source of nourishment (AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals; 2010). Made from any combination of milk, soy, rice, whey, hydrolyzed protein, starch and amino acids, with and without intact protein.

Lactose.—β-D-galactopyranosyl-(1→4)-D-glucose. CAS No. 63-42-3 (*see* Figure 1).

Limit of detection (LOD).—The lowest concentration or mass of analyte in a test sample that can be distinguished from a true blank sample at a specified probability level.

Limit of quantitation (LOQ).—The lowest level of analyte in a test sample that can be quantified at a specified level of precision.

Milk and milk products.—Milk is defined as the normal mammary secretion of a milk animal, intended for consumption as liquid milk or for further processing

Milk product is defined as a product obtained by any processing of milk. Although a milk product shall be made from milk, the definition does not hinder the milk from being subjected to various processing steps before it becomes an end product.

Composite milk product is a product of a milk product and other food(s) where the milk constituents are an essential part in terms of quantity of the final product. [Bulletin of IDF 397 (2005) *The Codex General Standard for the Use of Dairy Terms, Its Nature, Intent and Implications*]

Recovery.—Fraction or percentage of analyte that is measured 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 (in the same laboratory) and repeating during a short time period. Expressed as the repeatability standard deviation (SD_r); or % repeatability relative standard deviation ($\%RSD_r$).

Reproducibility.—Variation arising when identical test materials are analyzed in different laboratory by different operators on different instruments. 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 ($\%RSD_R$).

5 Method Performance Requirements

See Table 2.

6 System Suitability Tests and/or Analytical Quality Control

Suitable methods will include blanks, and appropriate check standards.

7 Validation Guidance

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

Method data packages must include relevant data regarding interferences and instabilities, such as listed in Table 2. Not all interferences are likely to occur in all matrices. Method developers are responsible for assessing interferences with the method.

8 Maximum Time-to-Results

None

9 Reference and Harmonization Materials

See Tables 3 and 4 and Figure 2.

Refer to Annex F: *Development and Use of In-House Reference Materials* in Appendix F: *Guidelines for Standard Method Performance Requirements*, 21st Ed. of the *Official Methods of Analysis of AOAC INTERNATIONAL* (2019). Available at http://www.eoma.aoac.org/app_f.pdf

Approved by the AOAC Stakeholder Panel on Strategic Food Analytical Methods (SPSFAM). Final Version Date: August 2018.

Table 1. Potential interferants

Other nontarget mono-, di-, and trisaccharides (especially lactulose and allolactose)
Enzymatic activity (beta-galactosidase)
Organic acid activity
Glucose with higher degrees of polymerization
Sugar alcohols to include:
Glycerol
Erythritol
Xylitol
Sorbitol
Mannitol
Maltitol
Lactitol
Isomalt
Hydroxylated compounds (nontargeted carbohydrates, sugar alcohols, sugar acids, sucralose, etc.)
Salts, such as sodium chloride
Amine-containing compounds (glucosamine HCl, amino acids, peptides, glycoproteins, etc.)

Table 2. Method performance requirements

	Infant formula	Milk, milk products, and products containing dairy ingredients	
Analytical range, mg/100 g	5–100	10–100	>100–2000
Recovery, %	85–115	85–115	90–110
RSD_r, %	≤10	≤10	≤7
RSD_R, %	≤15	≤15	≤10

Note: Requirements are for foods and beverages as received. For infant formula and adult nutritional products, concentrations apply to "ready-to-feed" liquids, reconstituted powders (for infant formula products, 25 g into 200 g water).

Table 3. Reference materials

No.	SRM name	Analyte	Value	U	Units	Value type
NIST SRM 2383a	Baby Food Composite	Lactose	0.5	0.1	%	Reference

Table 4. Harmonization materials

National Milk Laboratories (UK)
http://www.qclscientific.com/pdfs/Dairy%20Calibration%20Standards%20rev.4.pdf
MUVA (Germany)
https://www.muva.de/muva/web.nsf/id/pa_reference_materials_e.html

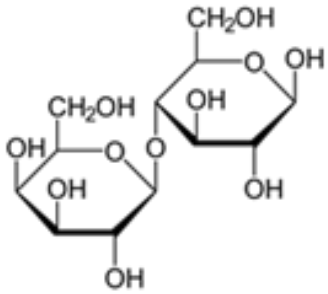

Figure 1. Lactose.

UHT MILK (LOW IN LACTOSE, LACTOSE FREE)						
muva-ML-2308	UHT-Milk (low in lactose) Best before: 06/2018	Lactose (monohydrate): via HPLC via Enzym. (Gal.) Galactose enzym. Glucose enzym.	 g/100g g/100g g/100g g/100g	 0,306 0,642 2,01 2,15	100 ml	25,00 €
muva-ML-2309	UHT-Milk (lactose-free, frozen) Best before: 06/2018	Lactose (monohydrate): via HPLC via Enzym. (Gal.) Galactose enzym. Glucose enzym.	 g/100g g/100g g/100g g/100g	 0,008 0,041 2,44 2,37	at least 40 ml	25,00 €
muva-CA-0904	Sodium Caseinate Best before: 02/2023	Fat Water Protein Lactose (monohydrate) Ash	g/100g g/100g g/100g g/100g g/100g	0,58 5,62 91,08 0,023 3,60	80 g	30,00 €

Figure 2. Reference and harmonization materials.