AOAC SMPR 2012.006

Standard Method Performance Requirements for Vitamin K in Pre-Blends, Pre-Mixes, and Pure Materials

1 Applicability

Determination of vitamin K, defined as the sum of *cis* and *trans* isomers of vitamin K_1 (phylloquinone or phytomenadione or phytonadione), dihydro-K_1, and vitamin K_2 (the menaquinone series), in food ingredients such as pre-blends, pre-mixes, and pure materials, including encapsulated and oil forms.

2 Analytical Technique

Chromatographic methods that utilize common instrumentation that are readily available worldwide.

3 Definitions

Pre-blends and pre-mixes.—Mixtures of one or more food additives, with food materials or water used as a carrier, and not intended for direct consumption by humans.

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).

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.

Table 1. Method performance requirements[a]

Analytical range	100 ppm–100%	
Limit of quantitation (LOQ)	≤100 ppm	
Repeatability (RSD_r)	0.01%	≤4%
	1%	≤2%
	100%	≤1%
Recovery	90 to 110% of mean spiked recovery over the range of the assay	
Reproducibility (RSD_R)	0.01%	≤8%
	1%	≤4%
	100%	≤2%

[a] Acceptance criteria are on the total analyte basis.

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)

Use suitable materials.

7 Validation Guidance

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

8 Maximum Time-to-Results

No maximum time.

Approved by the AOAC Stakeholder Panel on Strategic Food Analytical Methods (SPSFAM) on September 29, 2012. Final Version Date: September 28, 2012.