AOAC SMPR® 2016.014

Standard Method Performance Requirements (SMPRs) for Identification and Quantitation of Non-Animal-Derived Proteins in Dietary Supplements

Intended Use: Reference Method for cGMP Compliance

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 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 methods 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

Methods must identify and quantify one or more non-animal-derived protein(s) and their corresponding sources (Table 1) in the presence of potential adulterants (Table 2) in ingredients and finished dietary supplements.

3 Analytical Technique

Any analytical technique is acceptable.

4 Definitions

Protein.—Naturally occurring and synthetic polypeptides having molecular weights greater than about 10 000 daltons (the limit is not precise) (IUPAC definition).

Limit of quantitation (LOQ).—Minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.

Table 1. One or more recommended non-animal-derived proteins from these sources
Algae
Canola
Flax
Hemp
Pea
Potato
Pumpkin
Quinoa
Rice
Soy
Wheat

Table 2. Examples of adulterants
Melamine
Urea
Free amino acids
Creatine
Caffeine
Taurine
Surfactants
Peptides (less than 10000 daltons)
Nontarget proteins

Limit of detection (LOD).—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.

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.—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.

5 Method Performance Requirements

See Tables 3 and 4.

6 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.

7 Potential Reference Material(s)

Refer to Annex F: *Development and Use of In-House Reference Materials* in Appendix F: *Guidelines for Standard Method Performance Requirements*, *Official Methods of Analysis of AOAC INTERNATIONAL* (current edition), AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_f.pdf)

8 Validation Guidance

Data demonstrating method performance for the non-animal-derived proteins listed in Table 1 in the presence of the potential non-protein ingredients, including adulterants listed in Table 2, is recommended.

Appendix D: *Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis*, *Official Methods of Analysis of AOAC INTERNATIONAL* (current edition), AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_d.pdf)

Appendix F: *Guidelines for Standard Method Performance Requirements*, *Official Methods of Analysis of AOAC INTERNATIONAL* (current edition), AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_f.pdf)

Appendix K: *Guidelines for Dietary Supplements and Botanicals, Official Methods of Analysis of AOAC INTERNATIONAL* (current

Table 3. Method performance requirements (part 1)	
Parameter	Acceptable criteria
Analytical range, %	0.1–100
LOQ, %	0.05
LOD, %	0.025

Table 4. Method performance requirements (part 2)		
	Range, %	
	0.1–1	>1
Recovery, %	90–110	97–103
RSD_r, %	≤10	≤6
RSD_R, %	≤12	≤8

edition), AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_k.pdf)

9 Maximum Time-to-Result

None.

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