AOAC SMPR® 2017.009

Standard Method Performance Requirements (SMPRs) for Quantitation of Aloe Vera Characteristic Water-Soluble Main Constituents 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 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

Quantitation of characteristic water-soluble aloe vera main constituents and degradation products in the matrices listed in Table 1.

3 Analytical Technique

NMR, GC, colorimetric, GPC, or any analytical technique that meets the following method performance requirements is acceptable. It is expected that more than one technique will be required.

4 Definitions

Aloe vera main constituents and degradation products.—Aloe vera polysaccharides (acetylated 1, 4 beta glucomannan) is the signature component of aloe vera. Acetic acid is a degradation product of aloe vera, quantified as a measure of the level of de-acetylation of aloe vera polysaccharide (degradation product). Malic acid is a necessary component of aloe vera. Lactic acid is a product of malolactic fermentation (degradation product). Isocitrate is a marker constituent found exclusively in the plant's outer rind and used to identify the anatomical source of the leaf material being examined.

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

Table 1. Matrices

Tablets
Capsules
Liquids
Powders
Extracts
Plant products

Table 2. Method performance requirements (part 1)

Parameter	Ingredients (raw materials)	Finished products (solid)	Finished products (liquid; freeze-dried samples)[a]
LOQ, %	≤0.5	≤0.5	≤0.15
Analytical range, %	1–100	1–100	0.15–100

[a] Freeze drying is recommended.

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.

5 Method Performance Requirements

See Tables 2 and 3.

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)

Custom Analytics (Charles Metcalfe, Tel: (803) 499-4469, cem@calabs.us), Low-Molecular-Weight Pure Polysaccharides (80 000 daltons)

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* (20th Ed.), AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_f.pdf)

8 Validation Guidance

Data demonstrating that the candidate method meets the performance criteria for quantitation of aloe vera polysaccharides in the presence adulterants listed in Table 4 and the matrices listed in Table 1 should be submitted.

Pharmachem Labs may provide materials for evaluation.

Appendix D: *Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis*, *Official Methods of Analysis of AOAC INTERNATIONAL* (20th Ed.), AOAC

Table 3. Method performance requirements (part 2)

Parameter	Ingredients (raw materials) (1–100%)	Finished products (solid) (1–100%)	Finished products (liquid) (freeze-dried samples)	
			0.15–0.5%	≥0.5–100%
Rec., %	90–110	90–110	≥50	90–110
RSD_r, %	≤10	≤10	≤20	≤10
RSD_R, %	≤15	≤15	≤30	≤15

Table 4. Potential adulterants

Maltodextrin
Carageenan
Gum acacia
Locust gum

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* (20th Ed.), 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* (20th Ed.), AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoac.org/app_k.pdf). Also at *J. AOAC Int.* **95**, 268(2012) DOI: 10.5740/jaoacint.11-447

9 Maximum Time-to-Result

None.

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