DRAFT AOAC SPDS Aloe Vera SMPR, v6, 16 November 2016.

Quantitation of Aloe Vera Polysaccharides 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 total water soluble Aloe Vera main constituents and degradation products in the matrices listed in Table 4.

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.

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 1 and 2..

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 (add Charlie's info) 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*, 19th Edition of the AOAC INTERNATIONAL Official Methods of Analysis (2012). Available at: http://www.eoma.aoac.org/app_f.pdf

8. **Validation Guidance**:

Data demonstrating that the candidate method meets the performance criteria should be submitted for the adulterants listed in Table 3 and the matrices listed in Table 4.

Pharmachem Labs may provide materials for evaluation.

Appendix D: Guidelines for Collaborative Study Procedures To Validate Characteristics of a Method of Analysis; 19th Edition of the AOAC INTERNATIONAL Official Methods of Analysis (2012). Available at: http://www.eoma.aoac.org/app_d.pdf

Appendix F: Guidelines for Standard Method Performance Requirements; 19th Edition of the AOAC INTERNATIONAL Official Methods of Analysis (2012). Available at: http://www.eoma.aoac.org/app_f.pdf

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

Table 1: Method performance requirements (part 1).

Parameter	Ingredients (Raw Materials)	Finished Products - Solid	Finished Products – Liquid (Freeze dried samples)
LOQ (%)	≤ 0.5	≤ 0.5	≤ 0.15
Analytical Range (%)	1 – 100	1 – 100	0.15 – 100

Table 2: 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%
Recovery (%)	90 – 110	90 – 110	≤ 50	90 – 110
% RSD_r	≤ 10	≤ 10	≤ 20	≤ 10
% RSD_R	≤ 15	≤ 15	≤ 30	≤ 15

Table 3: Potential Adulterants

Maltodextrin
Carragennan
Gum acacia
Locust gum

Table 4 : List of Matrices

Tablets
Capsules
Liquids
Powders
Extracts
Plant products

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