DRAFT AOAC SPDS Aloe Vera SMPR, v5, 2016-12-08.

Identification of Aloe Vera in Dietary Supplements and Dietary Ingredients

Intended Use: Reference method for cGMP compliance.

1. **Purpose:** AOAC Standard Method Performance Requirements (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**:

   Identification of acetylated glucomannan polysaccharides derived from Aloe Vera in dietary ingredients as listed in Table 1 and dietary supplements as listed in Table 2. Candidate methods should be able to differentiate acetylated glucomannan polysaccharides derived from whole leaf and/or inner leaf products from gel.

3. **Analytical Technique**:
   Any analytical technique that meets the method performance requirements specified in this SMPR.

4. **Definitions**:

   Acetylated glucomannan polysaccharides.
   The signature component of Aloe Vera. A polysaccharide comprising of acetylated 1,4-ß-D-Glucosyl and D-Mannosyl Residues. CAS# 85507-69-3 (Aloe Vera Extract)

   Dietary Ingredients
   A vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients.[1]

   Dietary Supplements
   A product intended for ingestion that contains a "dietary ingredient" intended to add further nutritional value to (supplement) the diet. Dietary supplements may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders.

5. **Method Performance Requirements**:
   See table 4.

[1] Federal Food Drug and Cosmetic Act §201(ff) [U.S.C. 321 (ff)

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):**

Testing materials can be obtained from Charles Metcalfe, Custom Analytics.
Contact: +1(803) 499-4469 or cem@calabs.us

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**:
Information on analytical performance for all claimed matrixes must be submitted. Demonstrate ability to correctly identify acetylated glucomannan polysaccharides derived from Aloe Vera from the potential adulterants listed in table 3. Validation test samples should be blind coded, and randomly mixed with respect to presence and absence of target and potential adulterants.

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

Appendix N: ISPAM Guidelines for Validation of Qualitative Binary Chemistry Methods.

9. **Maximum Time-To-Result:** None

Table 1: Dietary Ingredients

Liquid
Powder
concentrates
purified polysaccharides
processed polysaccharides

Table 2: Dietary Supplements

Tablets
Capsules
Liquids
Powders
Extracts
Gummies
Softgels

Table 3: Potential Adulterants

Maltodextrin
Carragennan
Gum acacia
Locust gum

Table 4: Method performance requirements.

Selectivity Study	100% correct identification of glucomannan polysaccharides derived from Aloe Vera in the presence or absence of potential adulterants listed in table 3.*
*100% correct analyses are expected. Some aberrations may be acceptable if the aberrations are investigated, and acceptable explanations can be determined and communicated to method users.	