

Standard Method Performance RequirementsSM for Identification of Selected *Cinnamomum* spp. Bark in Dietary Supplement Raw Materials and/or Finished Products

Intended Use: Method for Dispute Resolution or Routine Surveillance

1 Applicability

Identification of individual selected *Cinnamomum* spp. bark (Table 1) in dietary supplement raw materials and/or finished products.

2 Analytical Technique

Any analytical technique(s) based on chemical and/or genetic fingerprints that identifies *Cinnamomum* spp. bark and meets the following method performance requirements is/are acceptable.

3 Definitions

Identification.—Characterization of the substance being analyzed, including its chemical, mineral, or biological classification, as applicable. In many investigations the identity of the analyte is assumed and the correctness of the assumption is merely confirmed.

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 {United States Federal Food Drug and Cosmetic Act §201(ff) [U.S.C. 321 (ff)]}.

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.

Selected *Cinnamomum* species (Table 1).—*Cinnamomum* species identified by the AOAC Cinnamon Working Group that are

Table 1. Selected *Cinnamomum* spp.

<i>Cinnamomum verum</i> Presl (syn. <i>C. zeylanicum</i> Nees) [“True “cinnamon, Ceylon cinnamon, Mexican cinnamon]
<i>C. cassia</i> Presl (<i>C. aromaticaum</i>) [Chinese cinnamon, Cassia cinnamon, Cassia lignea]
<i>C. burmannii</i> Blume [Indonesian cinnamon, Korintje cinnamon, Pandang cinnamon]
<i>C. loureirii</i> Nees [Saigon cinnamon, Vietnamese cinnamon, Vietnamese cassia]
<i>C. tamala</i> (Buch.-Ham.) Nees & Eberm. [Indian Bay Leaf, Indian cassia bark, Tamala cassia, Indian cassia lignea]
<i>C. ramulus</i> [Cinnamon twig, Cassia twig]

the focus of methods for identification by chemical and/or genetic profiles.

Exclusivity study.—Study involving nontarget compounds, which are potentially cross-reactive, that shall not be detected, enumerated, or identified by the test method.

4 Method Performance Requirements

See Table 2.

5 System Suitability Tests and/or Analytical Quality Control

Methods will include a protocol to demonstrate sensitivity and specificity.

6 Reference Material(s)

Refer to Annex F: *Development and Use of In-House Reference Materials* in Appendix F: *Guidelines for Standard Method Performance RequirementsSM, Official Methods of Analysis of AOAC INTERNATIONAL* (2012) 19th Ed. Available at http://www.eoma.aoc.org/app_f.pdf.

Select authentic materials from vouchered and/or accredited sources.

Hildreth, J. et al. (2007) *Anal. Bioanal. Chem.* **389**, 13–17

Applequist, W., & Miller, J.S. (2013) *Anal. Bioanal. Chem.* **405**, 4419–4428

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Table 2. Method performance requirements

	Study	Parameter ^a	Parameter requirements	Minimum acceptable results
Single-laboratory validation	Matrix study	POI	Minimum of 33 replicates ^b representing all selected <i>Cinnamomum</i> species in Table 1 plus all nontarget compounds listed in Table 3	90% POI ^c of the pooled data for all selected species
Multi-laboratory validation	Matrix study ^d	LPOI	Use Appendix N: <i>ISPM Guidelines for Validation of Qualitative Binary Chemistry Methods^e</i>	≥0.95 ^c

^a POI = Probability of identification. The proportion of positive analytical outcomes for an identification method for a given matrix at a given analyte level or concentration. LPOI = Laboratory probability of identification. The combined collaborative study proportion of positive analytical outcomes for an identification method for a given matrix at a given analyte level or concentration.

^b 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.

^c 95% confidence interval.

^d Multi-laboratory validation matrix study (LPOI) are not required for First Action *Official Methods of Analysis* approval.

^e *Official Methods of Analysis of AOAC INTERNATIONAL* (2012) 19th Ed. Available at http://www.eoma.aoc.org/app_n.pdf.

Table 3. Exclusivity panel

Wheat flour
Rice starch
Sawdust
Non-cinnamon tree bark
Ground walnut shell
Clove
Sugar
Galanga rhizome
Caramel
Garlic extract
Fenugreek seed extract
Green tea extract
Ginseng (American, Asian, Dwarf, Himalayan, Japanese)
Aloe
Jobba seed extract
Kelp extract
Emblic extract
Gymnea extract
Jambolan extract
Neem bark extract
Turmeric extract
Cayenne extract
Bilberry extract
Guggul extract

7 Validation Guidance

Appendix K: *Guidelines for Dietary Supplements and Botanicals, Official Methods of Analysis of AOAC INTERNATIONAL* (2012) 19th Ed. Available at http://www.eoma.aoac.org/app_k.pdf.

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

Method developers must submit validation data for all of the selected *Cinnamomum* species listed in Table 1 and all nontarget compounds listed in Table 3 for First Action *Official Methods*SM consideration.

8 Maximum Time-to-Result

No maximum time to result.

Approved by the AOAC Stakeholder Panel on Dietary Supplements (SPDS). Effective Date: March 19, 2015. Final Version Date: June 15, 2015.