

Standard Method Performance Requirements (SMPRs) for Identification of Type-A Proanthocyanidins in Cranberry-Based Foods and Dietary Supplements

Intended Use: Consensus-Based Reference Method

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*SM or *AOAC Official Methods of Analysis*SM, and can be used as acceptance criteria for verification at user laboratories.

2 Applicability

The method will be able to identify the presence of Type-A proanthocyanidin in cranberry (*Vaccinium macrocarpon*) in one or more of the following: fruit, juice, beverage, dried cranberry fruit, cranberry sauce, ingredients (concentrates, extracts, powders, and presscake); or dietary supplements (listed in Table 1).

3 Analytical Technique

Any analytical technique that detects the analytes of interest and meets the method performance requirements is acceptable.

4 Definitions

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.

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.

Table 1. Examples of dietary supplements

Capsules (containing dried cranberry fruit powder, dry extract)
Extracts
Gummies
Liquids
Powders
Softgel capsules (oil and/or water-based)
Tablets (containing dried cranberry fruit powder, dry extract)
Tinctures

Table 2. Method performance requirements

Selectivity study	90% probability of identification with 95% confidence (33 correct identifications out of 33 samples known to contain Type-A proanthocyanidin) ^a
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^a Some aberrations may be acceptable if the aberrations are investigated, and acceptable explanations can be determined and communicated to method users.

5 Method Performance Requirements

See Table 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 Reference Material(s)

SRM 3281 Cranberry (Fruit)*
 SRM 3282 Low Calorie Cranberry Juice Cocktail*
 SRM 3283 Cranberry Extract*
 SRM 3284 Cranberry-Containing Solid Oral Dosage Form*

* Characterized for organic acids, not proanthocyanidins, but provides a standard, homogeneous material.

Contact Dr. Catherine Rimmer, Research Chemist, NIST, for materials at email: catherine.rimmer@nist.gov or Tel: (301) 975-3651.

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*

Table 3. Sources of non-Type-A proanthocyanidins

Tier 1 (required)
Aple (<i>Malus domestica</i> Borkh.)
Grape skins, grapeseed extract (<i>Vitis vinifera</i> L.)
Black chokeberry [<i>Aronia melanocarpa</i> (Michx.) Elliott] or Purple chokeberry [<i>Aronia arbutifolia</i> (L.) Pers.]
Tier 2 (additional)
<i>Ginkgo biloba</i> L.
Hawthorn [<i>Crataegus laevigata</i> (Poir.) DC., <i>Crataegus monogyna</i> Jacq.]
Dragon's blood (<i>Croton lechleri</i> Müll.Arg.)
Japanese horse chestnut (<i>Aesculus turbinata</i> Blume)
Pine bark (<i>Pinus sylvestris</i> L., <i>Pinus pinaster</i> Aiton)
Plum (<i>Prunus domestica</i> L.)
Other <i>Vaccinium</i> species: huckleberry (<i>V. ovatum</i> Pursh), highbush blueberry (<i>V. corymbosum</i> L.), lowbush blueberry (<i>V. angustifolium</i> Aiton), lingonberry (<i>V. vitis-idaea</i> L.), European cranberry [<i>V. (Turcz. ex Rupr.) Schmalh.</i>]
Cocoa (<i>Theobroma cacao</i> L.)
Barley (<i>Hordeum vulgare</i> L.)
Sorghum [<i>Sorghum bicolor</i> (L.) Moench]
Blackcurrant (<i>Ribes nigrum</i> L.)
Gooseberry (<i>Ribes uva-crispa</i> L.)
Common bean (<i>Phaseolus vulgaris</i> L.)
Hazelnut (<i>Corylus avellana</i> L.)
Pecan [<i>Carya illinoensis</i> (Wangenh.) K.Koch]
Pistachio (<i>Pistacia vera</i> L.)

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8 Validation Guidance

Information on analytical performance for all claimed matrixes must be submitted. Method developers should evaluate at least 33 samples known to contain Type-A proanthocyanidin and at least 33 samples that contain non Type-A proanthocyanidin. Validation data must include examples of non-Type-A matrices listed in tier 1 of Table 3. Additional non-Type-A matrices are listed in tier 2 of Table 3. Validation test samples should be blind coded, and randomly mixed with respect to presence or absence of Type-A proanthocyanadin.

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

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

9 Maximum Time-to-Result

None.

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