AOAC SMPR® 2017.003

Standard Method Performance Requirements (SMPRs) for Quantitation of Proanthocyanidin Content in Cranberry Fruit, Juice, Beverage, Dried Cranberry, Cranberry Sauce, Ingredients (Concentrates, Extracts, and Powders), and Dietary Supplement Formulations

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

The method will be able to quantify total proanthocyanidin content as the sum of all extractable oligomers (>DP2) and polymers present 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 (Table 1).

3 Analytical Technique

Any analytical technique(s) that measures the analytes of interest and meets the following method performance requirements is/are acceptable.

4 Definitions

Cranberry proanthocyanadins.—A mixture of oligomeric and polymeric flavan-3-ols, primarily epicatechin and catechin, of the A and B type.

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 {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.

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

Quantitative method.—Method of analysis which response is the amount of the analyte measured either directly (enumeration in a mass or a volume), or indirectly (color, absorbance, impedance, etc.) in a certain amount of sample.

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 Reference Material(s)

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

Appendix D: *Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis*, *Official Methods*

Table 1. Examples of dietary supplements

Capsules
Extracts
Liquids
Powders
Softgel capsules
Tablets
Tinctures
Gummies

Table 2. Method performance requirements (part 1)

Parameter	Requirement
Limit of quantitation (LOQ; %)	≤0.01
Analytical range, %	≤0.03–55

Table 3. Method performance requirements (part 2)

	Liquids		Solids	
Range, %	0.03–15	>15–55	0.03–15	>15–55
Rec., %	97–103	97–103	90–107	97–103
RSD_r, %	≤10	≤5	≤15	≤10
RSD_R, %	≤15	≤8	≤20	≤15

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

9 Maximum Time-to-Result

None.

Approved by the AOAC Stakeholder Panel on Strategic Food Analytical Methods (SPSFAM) on March 13, 2017. Final Version Date: March 13, 2017.