AOAC SMPR® 2018.007

Standard Method Performance Requirements (SMPRs®) for Identification of Skullcap in Raw Materials, Skullcap-Based Dietary Ingredients, 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 methods 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 skullcap in raw materials and/or dietary ingredients.

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.

Skullcap.—For the purposes of this SMPR, skullcap species include *Scutellaria lateriflora* aerial parts and *Scutellaria baicalensis* roots.

5 Method Performance Requirements

See Table 1.

6 System Suitability Tests and/or Analytical Quality Control

Methods will include a protocol to demonstrate resolution sensitivity and repeatability.

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*, 20th Ed. of the *Official Methods of Analysis of AOAC INTERNATIONAL* (2016). Available at: http://www.eoma.aoac.org/app_f.pdf

8 Validation Guidance

Information on analytical performance for all claimed matrixes (listed in Table 2) must be submitted. Method developers should evaluate at least 33 samples known to contain skullcap and at least 33 samples that contain one of the exclusion species listed in Table 3. Validation data must include examples of authentic skullcap materials and also examples of materials containing exclusion species from Table 3. All species in tier 1 are required, all species in tier 2 are desirable but optional. Validation test samples should be blind coded and randomly mixed with respect to presence or absence of skullcap and exclusion panel species.

Appendix D: *Guidelines for Collaborative Study Procedures to Validate Characteristics of a Method of Analysis,* 20th Ed. of the *Official Methods of Analysis of AOAC INTERNATIONAL* (2016). Available at: http://www.eoma.aoac.org/app_d.pdf

Appendix F: *Guidelines for Standard Method Performance Requirements*, 20th Ed. of the *Official Methods of Analysis of AOAC INTERNATIONAL* (2016). Available at: http://www.eoma.aoac.org/app_f.pdf

Appendix K: *Guidelines for Dietary Supplements and Botanicals*, 20th Ed. of the *Official Methods of Analysis of AOAC INTERNATIONAL* (2016). Available on line at: http://www.eoma.aoac.org/app_k.pdf

9 Maximum Time-to-Result

None

Approved by the AOAC Stakeholder Panel on Dietary Supplements (SPDS). Final Version Date: March 16, 2018.

Table 1.	Method performance requirements
Selectivity study	90% Probability of identification with 95% confidence (33 correct identifications out of 33 samples known to contain skullcap)[a]. *See* Validation Guidance in Section 8 of this document.
[a] Some aberrations may be acceptable if the aberrations are investigated, and acceptable explanations can be determined and communicated to method users.	

Table 2.	Examples of dietary ingredients and supplements
Capsules
Extracts
Liquids
Powders
Softgel capsules
Tablets
Tinctures
Blended finished products

Table 3.	Exclusion species
Tier 1 (required)
S. incana
Teucrium canadense
T. chamaedrys
Tier 2 (additional)
Scutellaria baicalensis (aerial parts)
S. galericulata
S. ovata