

Standard Method Performance Requirements (SMPRs®) for Determination of Free Bisphenol A (BPA) in Commercially Packaged Ready-to-Consume Carbonated and Noncarbonated Water and Nonalcoholic Beverages

Intended Use: Surveillance and Monitoring by Trained Technicians

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 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

Determination of free bisphenol A (BPA) in commercially packaged ready-to-consume carbonated and noncarbonated water and nonalcoholic beverages listed in Table 1.

3 Analytical Technique

Any analytical technique that meets the following method performance requirements is acceptable.

4 Definitions

Accuracy (corresponds to the VIM definition for “trueness”).—The closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value.

Bisphenol A (BPA).—IUPAC name: 4,4'-(Propane-2,2-diyl)diphenol. CAS Registry No.: 80-05-7. See Figure 1 for chemical structure.

Limit of detection (LOD).—The smallest amount or concentration of an analyte that can be estimated with acceptable reliability. Estimated as: $LOD = \text{blank mean} + 3 \text{ standard deviations of } 10 \text{ independent analyses of blank or blank spiked at low level (to be agreed upon by study directors; if there is no detectable blank signal)}$. See reference to Appendix L in section 8 Validation Guidance.

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

result. Determined as: $LOQ = \text{blank mean} + 10 \text{ standard deviations (concentration of blank to be } <10\% \text{ of the estimated LOQ)}$. See reference to Appendix L in section 8 Validation Guidance.

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).

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)

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* (2016) 20th Ed., AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoc.org/app_f.pdf)

8 Validation Guidance

Method developers must submit data (LOQ, accuracy...) on at least one of the matrices in Table 1. Data from as many of the other beverages listed in Table 1 would be desirable. It is desirable to also have data on products containing coffee/dairy.

RSD_{R,s} may be calculated from pooled results from the different matrices in Table 1.

Developers should submit the method's procedures used for background assessment and control, and frequency of analysis of method blanks.

Appendix F: *Guidelines for Standard Method Performance Requirements, Official Methods of Analysis of AOAC INTERNATIONAL* (2016) 20th Ed., AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoc.org/app_f.pdf)

Appendix L: *AOAC Recommended Guidelines for Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Single-Laboratory Validation, Official Methods of Analysis of AOAC INTERNATIONAL* (2016) 20th Ed., AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoc.org/app_l.pdf)

9 Maximum Time-to-Result

No maximum time.

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Table 1. Nonalcoholic beverages

Carbonated soft drinks, regular (full calorie)
Carbonated soft drinks, diet
100% Juices, with pulp
100% Juices, without pulp
Teas
Dairy-based coffee drinks
Sports drinks (from a hydration standpoint)
Energy drinks
Grain-based beverages (e.g., soy milk, rice milk, nut milk, etc.)
Meal replacement beverages

Table 2. Method performance requirements

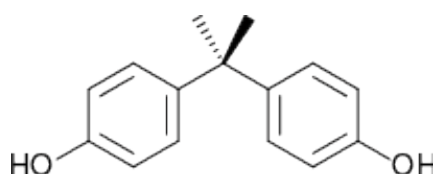
LOD	≤0.1 µg/L
LOQ	≤0.5 µg/L

Table 3. Method performance requirements

Analytical range, µg/L ^{a,b}	<2	2–5	5–20
Accuracy, %	60–140	80–120	80–120
RSD _r , %	≤20	≤10	≤5
RSD _R , %	≤40	≤20	≤10

^a Units are expressed as µg/L as weight/volume.

^b Concentration in the ready-to-drink product.

**Figure 1. Molecular structure of bisphenol A.**