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Ref. No.: CML-HRM-1012A/10
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Certificate of Analysis

CERTIFIED REFERENCE MATERIAL
HRM – 1012A

Acesulfame Potassium

Batch Number
STY-0055-001

Description
A unit of the certified reference material (CRM) consists of 250 mg of acesulfame potassium in a screw-capped amber vial. Quantitative proton nuclear magnetic resonance (^{1}H qNMR) approach was adopted to determine the mass fractions (mg/g) of acesulfame potassium in the reference material using a dimethyl sulfone CRM from National Measurement Institute (NMI, Australia) as internal standard.

The CRM was produced with reference to the requirements set out in ISO/IEC 17025:2017 [1], ISO 17034:2016 [2] and ISO Guide 35:2017 [3].

Certified Mass Fraction Values
A certified value is a value for which a laboratory has the highest confidence in its accuracy. The certified mass fraction value given below is based on the results obtained by the qNMR approach:

Certified Mass Fraction Value: 999.2 ± 5.0 mg/g

The mass fraction value is expressed as the certified value ± the expanded uncertainty.

The uncertainty listed with the certified value is an expanded uncertainty about the mean, with coverage factor 2, calculated at approximately 95% confidence. The certified value has an associated measurement uncertainty where uncertainty contribution from characterisation of the material (u_{char}), uncertainty in the homogeneity of the material (u_{bb}) and uncertainty in the stability of the material (u_{stab}) were considered. The u_{char} was evaluated by combining uncertainties from method precision, purity of the internal standard, molecular weight of acesulfame potassium, molecular weight of dimethyl sulfone and weighing, in accordance with ISO/IEC Guide 98-3:2008 [4].

Homogeneity

Homogeneity testing on acesulfame potassium and structurally-related organic compounds was performed on two sub-samples taken from eleven using (a total of twenty-two samples) using high performance liquid chromatography with diode array detection (HPLC-DAD). The sample size taken for homogeneity testing was approximately 5 mg to produce a solution with acesulfame potassium concentration of about 2 mg/g. No significant differences in the between and within-bottle variances were found using one-way ANOVA at 95 % confidence level [3]. Thus, the material was regarded to be sufficiently homogeneous.

Stability

The short-term stability of acesulfame potassium was studied. The material was stored at 50 ^{o}C (maximum allowable transportation temperature) over a period of up to 30 days. The results showed that acesulfame potassium was stable over the study period.

The long-term stability of acesulfame potassium at room temperature (18 °C to 25 °C) was evaluated on three occasions over a period of up to 3 months after preparation. The results showed that acesulfame potassium was stable over the study period.

Validity of Certified Mass Fraction Values

The certified mass fraction values are valid within their respective measurement uncertainties until **16 Apr 2026**, provided that the CRM is subjected to the same handling and storage conditions as stated in this Certificate of Analysis (COA). The validity of the certified mass fraction value has been confirmed using a 500 MHz NMR (Bruker Avance Ascend 500) at the Chemical Metrology Laboratory, HSA.

The CRM will be continuously monitored during the validity period to determine if any substantive change to the certified values has occurred. If necessary, its user will be advised or an updated COA may be issued when the property value of the CRM is found to have changed.

Analytical Methods

The determination of the purity of the acesulfame potassium reference material was carried out using a 500 MHz Bruker Ultra Shield NMR at the Department of Chemistry, National University of Singapore. Dimethyl sulfone was used as the internal standard for the determination. The certified value was calculated from the mean of 6 results obtained from one determination each on the 6 sub-samples (about 40 mg each) prepared from the CRM and the internal standard.

The main counter ion present in the compound was confirmed to be potassium using Inductively Coupled Plasma Mass Spectrometry (ICP-MS).

Metrological Traceability

The certified mass fraction value is traceable to the International System of Units (SI) through the use of dimethyl sulfone CRM (QNMR002 from NMI, Australia).

Intended Use

The CRM is intended for use as a calibrant or quality control (QC).

Instructions for Use

Prior to use, the material should be equilibrated to room temperature and rotated gently before sampling. After use, the bottle should be tightly recapped to avoid exposure to moisture and light. The minimum sample size for each use should be about 5 mg.

Storage

The CRM should be properly sealed and stored at a temperature of 18 °C to 25 °C in its original bottle. Exposure to moisture and light should be avoided.

Safety Precautions for Users

Treat the material as hazardous substance. Use appropriate work practices when handling the material, in order to avoid skin or eye contact or ingestion.

Further Information

Please direct all enquiries regarding this CRM to the contact provided in this COA.

References

1. ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories.
2. ISO 17034:2016 General requirements for the competence of reference material producers.
3. ISO Guide 35:2017 Reference materials – Guidance for characterisation and assessment for homogeneity and stability.
4. ISO/IEC Guide 98-3:2008 Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995).

Certificate Revision Records

Certificate of Analysis CML-HRM-1012A/02 replaces Certificate CML-HRM-1012A/01 issued on 16 Apr 2015.

Certificate of Analysis CML-HRM-1012A/03 replaces Certificate CML-HRM-1012A/02 issued on 18 Mar 2016.

Certificate of Analysis CML-HRM-1012A/04 replaces Certificate CML-HRM-1012A/03 issued on 03 Apr 2017.

Certificate of Analysis CML-HRM-1012A/05 replaces Certificate CML-HRM-1012A/04 issued on 12 Mar 2018.

Certificate of Analysis CML-HRM-1012A/06 replaces Certificate CML-HRM-1012A/05 issued on 26 Mar 2019.

Certificate of Analysis CML-HRM-1012A/07 replaces Certificate CML-HRM-1012A/06 issued on 27 Mar 2020.

Certificate of Analysis CML-HRM-1012A/08 replaces Certificate CML-HRM-1012A/07 issued on 16 Feb 2021.

Certificate of Analysis CML-HRM-1012A/09 replaces Certificate CML-HRM-1012A/08 issued on 04 Apr 2022.

Certificate of Analysis CML-HRM-1012A/10 replaces Certificate CML-HRM-1012A/09 issued on 16 Feb 2023.

Note

HSA does not assume any liability with respect to any loss caused by improper use and/or storage of the reference material by the customer.

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