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Ref. No.: CML-HRM-1034A/01
Date of Issue: 20 Apr 2026

Certificate of Analysis

CERTIFIED REFERENCE MATERIAL
HRM – 1034A

Dexamethasone

Batch Number
STY-0203-001

Description
A unit of the certified reference material (CRM) consists of about 150 mg of dexamethasone ($C_{22}H_{29}FO_5$) in a screw-capped amber glass vial. Quantitative proton nuclear magnetic resonance (^{1}H qNMR) approach was adopted to determine the mass fraction (mg/g) of dexamethasone ($C_{22}H_{29}FO_5$) using a methyl paraben CRM (HRM-1003A) from the Health Sciences Authority (HSA), Singapore 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 33405:2024 [3].

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

Certified Mass Fraction Value: 992 ± 15 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 (approximately 95 % confidence). The certified value has an associated measurement uncertainty attributed to uncertainty contribution from the 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}). The u_{char} was evaluated by combining uncertainties from method precision, purity of the internal standard, molecular weight of dexamethasone, molecular weight of internal standard, weighing and bias from factor due to different measurement days, in accordance with ISO/IEC Guide 98-3:2008 [4].

Homogeneity

Homogeneity testing on the dexamethasone content was performed on two sub-samples taken from eleven bottles (a total of 22 sub-samples) using qNMR technique. The minimum sample size taken for homogeneity testing was approximately 10.4 mg. 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. The u_{bb} was evaluated from uncertainty due to between-bottle inhomogeneity.

Stability

Short-term stability of dexamethasone was studied. The material was stored at 50 °C (maximum allowable transportation temperature) for up to 14 days. The results showed that dexamethasone was stable over the study period.

Long-term stability of dexamethasone was evaluated at storage temperature (2 to 8 °C) on three occasions over a period of up to 3 months after preparation. The results showed that dexamethasone was stable over the study period. The u_{stab} was evaluated from the standard error of the slope.

Validity of Certified Mass Fraction Value

The certified mass fraction value is valid within its measurement uncertainty until **20 Apr 2027**, provided that the CRM is subjected to the same handling and storage conditions as stated in this Certificate of Analysis (COA).

The CRM will be continuously monitored during the validity period to determine if any substantive change to the certified value 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 dexamethasone was carried out using a 500 MHz NMR (Bruker Avance Ascend 500) at the Chemical Metrology Laboratory, HSA. Methyl paraben CRM (HRM-1003A) from HSA was used as the internal standard for the determination. The certified mass fraction was calculated from the mean of 22 results obtained from one determination each on the 22 sub-samples prepared from the CRM and the internal standard.

Metrological Traceability

The certified mass fraction is traceable to the International System of Units (SI) through the use of methyl paraben CRM (HRM-1003A) from HSA.

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 must be tightly re-capped immediately and protected from moisture and light. The minimum sample size for each use should be approximately 10.4 mg. If results differ from certified value in subsequent sampling, customers are advised to purchase a new CRM.

Transport and Storage

HRM-1034A is transported in ambient temperature. Upon receipt, the material should be stored at a temperature of 2 to 8 °C in its original bottle. Exposure to moisture and light should be avoided. Users should comply to their local regulations regarding the import, usage and disposal of dexamethasone.

Health and Safety Information

Treat the material as hazardous substance. Use appropriate work practices when handling the material, in order to avoid skin or eye contact, ingestion or inhalation of dusts. The Safety Data Scheet (SDS) for this material is provided separately and contains essential safety and handling information.

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 33405:2024 Reference materials – Approaches for characterisation and assessment of 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 Record

Certificate Ref. No.	Date of issue	Reason for issuance
CML-HRM-1034A/01	20 Apr 2026	Issuance of first certificate

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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