Date of Shipment: Xxxxx xx, 20xx

6007a00-090324-220324

National Institute of Advanced Industrial Science and Technology

National Metrology Institute of Japan

Reference Material Certificate

NMIJ CRM 6007-a

No. +++

Hydrocortisone

This certified reference material (CRM) is produced in accordance with the NMIJ's management system and is in compliance with ISO 17034 and ISO/IEC 17025. This CRM is primarily intended for use in calibrating the analytical instruments and reagents, controlling the precision of analyses, and validating analytical methods and instruments.

Certified Value

The certified value of this CRM for the purity (in mass fraction) is given in the table below. The uncertainty of the certified value is the expanded uncertainty obtained by multiplying the combined standard uncertainty by a coverage factor (k) of 2, and it is the half-width of an interval estimated to have a level of confidence of approximately 95 %.

Substance	CAS No.	Certified value, Mass fraction (kg/kg)	Expanded uncertainty, Mass fraction (kg/kg)
Hydrocortisone (11β,17,21-trihydroxypregn-4-ene-3,20-dione)	50-23-7	0.993	0.003

Analysis

The certified value of this CRM was determined based on the measurement results of the Karl Fischer titration, the head space-gas chromatography-mass spectrometry (HS-GC/MS), the high performance liquid chromatography with ultra violet detector (HPLC-UV) and the HPLC with corona charged aerosol detector (HPLC-CAD).

Metrological Traceability

The certified value of this CRM is determined by measuring the mass fractions of impurities, including water, ethanol, identified steroid compounds and unidentified organic impurities, and subtracting the sum of these values from 1. The purity of each material used for calibration is evaluated at NMIJ. The certified value, therefore, is traceable to the International System of Units (SI).

Expiration of Certification

This certificate is valid for one year from the date of shipment, provided that this CRM is stored in accordance with the instructions given in this certificate.

Description of the material

This CRM is high-purity hydrocortisone in the form of a white powder. An amber glass vial is filled with 200 mg of this CRM, and it is packaged in an aluminum-laminated bag.

Instructions for Storage

This CRM should be kept at a temperature between 15 °C and 25 °C in a clean light-shielded place. It is recommended to store this CRM at a temperature around 5 °C, if storage for a longer period is needed.

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Instructions for Use

The bottle should be allowed to warm to room temperature before opening. This CRM should be used promptly once a bottle is opened. Considering the homogeneity, a minimum sample size(mass) of 10 mg should be used to ensure valid results.

Precautions for Handling

This CRM is for laboratory use only. Refer to the safety data sheet (SDS) on this CRM before use.

Preparation

This CRM was prepared by Wako Pure Chemical Industries, Ltd. The purified hydrocortisone was bottled into vials under the argon gas atmosphere, and each vial was sealed in an aluminum-laminated bag.

Technical Information

The values given below are not certified but technical information obtained at the certification process. Moisture measured by the Karl Fischer titration is 0.18 g/kg. Ethanol as residual solvent measured by the HS-GC/MS is 1.4 g/kg. Cortisone (17,21-dihydroxypregn-4-ene-3,11,20-trione), 6-dehydrocortisol (11β,17,21-trihydroxypregn-4,6-diene-3,20-dione), 5α-dihydrocortisol (11β,17,21-trihydroxy-5α-pregnane-3,20-dione) and prednisolone (11β,17,21-trihydroxypregna-1,4-diene-3,20-dione) by HPLC-UV were 0.30, 2.7, 0.41 and 0.14 g/kg, respectively.

NMIJ Analysts

The technical manager for this CRM is TAKATSU A., and production manager is KAWAGUCHI M., and the analysts are KAWAGUCHI M., KITAMAKI Y., SAKAMOTO T. and SAEKI M.

Information

If substantive technical changes occur that affect the certification before the expiration of this certificate, NMIJ will notify the registered customers. Customer registration on the NMIJ Website (given below) will facilitate notification. Technical reports regarding this CRM can be obtained from the contact details given below.

Reproduction of Certificate

In reproducing this certificate, it should be clearly indicated that the document is a copy.

April 1, 2020

ISHIMURA Kazuhiko
President
National Institute of Advanced Industrial Science and Technology

If you have any questions about this CRM, please contact:
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Revision history
April 1, 2015: “Metrology Management Center” was renamed to “Center for Quality Management of Metrology.”
April 1, 2018: The expanded uncertainty was changed to 0.003 kg/kg. The description in “Expiration of Certification” was changed to “one year from the date of shipment.”.