

National Institute of Advanced Industrial Science and Technology

National Metrology Institute of Japan



Reference Material Certificate

NMIJ CRM 6018-a
No. +++

L-Lysine Monohydrochloride

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 used in amino acid analysis. It is also intended for controlling the precision of analysis and for validating analytical methods or instruments.

Certified Values

The certified value for the purity of L-lysine (expressed as mass fraction of L-lysine monohydrochloride) is given in the table below. The uncertainty of the certified value is the half-width of the expanded uncertainty interval calculated using a coverage factor (k) of 2, which gives a level of confidence of approximately 95 %. Purity (in mass fraction) of L-lysine is given as follows.

	CAS No.	Certified value, Mass fraction (kg/kg)	Expanded uncertainty, Mass fraction (kg/kg)
L-Lysine monohydrochloride ((2S)-2,6-diaminohexanoic acid monohydrochloride)	657-27-2	0.998	0.002

The certified value and expanded uncertainty of lysine (expressed as mass fraction of lysine monohydrochloride) without enantiomeric separation is given in the table below, where the mass fraction of D-lysine is subtracted. The uncertainty of the certified value is the half-width of the expanded uncertainty interval calculated using a coverage factor (k) of 2, which gives a level of confidence of approximately 95 %.

	Certified value, Mass fraction (kg/kg)	Expanded uncertainty, Mass fraction (kg/kg)
Lysine monohydrochloride (without enantiomeric separation)	0.998	0.002

Analysis

The certified value expressed as the mass fraction of L-lysine monohydrochloride was determined by multiplying the mass fraction of lysine by the ratio of the molecular weight of lysine and lysine monohydrochloride. The mass fraction of lysine was determined resulting from non-aqueous acidimetric titration, nitrogen determination by the Kjeldahl method, and impurity determination by high-performance liquid chromatography. Impurities of amino acids were analyzed by LC with fluorescence detection after derivatization using o-phthalaldehyde (OPA) and by liquid chromatography mass spectrometry (LC/MS). Impurities of amino acids having an influence on the purity of L-lysine were not detected. Unidentified impurities were quantified by LC with charged aerosol detector (LC-CAD). D-lysine was quantified by LC/MS using a chiral resolution column.

Metrological Traceability

The certified value was determined by titrimetry as the primary method of measurement with NMIJ CRM 3001-a (potassium hydrogen phthalate) and NMIJ CRM 3005-a (sodium carbonate) as the primary standards and by impurity determination using HPLC. The certified value is traceable to the International System of Units (SI).

Mutual Recognition Arrangement under Meter Convention

The certified value and expanded uncertainty of this CRM without enantiomeric separation (mass fraction) is consistent with the calibration and measurement capabilities (CMCs) that are included in Appendix C of the Mutual Recognition Arrangement (MRA) drawn up by the International Committee for Weights and Measures (CIPM). Under the MRA, all participating institutes recognize the validity of each other's calibration and measurement certificates for the quantities, ranges and measurement uncertainties specified in Appendix C (as for Appendix C of MRA, see <http://kcdb.bipm.org/AppendixC/default.asp>).

Expiration of Certification

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

Sample Form

This CRM is in the form of a white powder. This CRM of 0.5 g in net volume is kept in an amber glass vial and the vial is sealed in an aluminum-laminated plastic bag.

Homogeneity

The homogeneity of the CRM was measured by acidimetric titration, analyzing 10 vials randomly selected from 400 vials. The homogeneity is reflected in the uncertainty of the certified value.

Instructions for Storage

This CRM should be stored at a temperature between 15 °C and 25 °C in a clean desiccator and shielded from light.

Instructions for Use

From the homogeneity, a minimum sample mass of 100 mg should be used. Because of the hygroscopicity of the material, it should be used under dry conditions and promptly once the vial is opened. Opening and usage at a relative humidity of less than 70 % are strongly recommended. This CRM is for laboratory use only and not for in vivo use. Refer to the safety data sheet (SDS) on this CRM before use.

Preparation

Preparation of the material was performed by Wako Pure Chemical Industries, Ltd. Highly purified L-lysine monohydrochloride provided by AJINOMOTO Co., Inc. was dried and bottled into vials under argon atmosphere. Each vial was sealed in an aluminum-laminated bag.

Technical Information

At the time of certification, moisture was determined by Karl Fischer coulometric titration to be 0.52 g/kg. The mass fraction of D-lysine monohydrochloride determined by LC/MS using a chiral resolution column was 0.35 g/kg. The quantification results by ion chromatography suggested that the amount of chloride ion is equal to that of lysine.

NMIJ Analysts

The technical manager for this CRM is TAKATSU A. and the production manager is KATO M. The analysts are YAMAZAKI T., KATO M., KATO H., EYAMA S., GOTO M. and YOSHIOKA M.

Information

If substantive technical changes occur that affect the certification before the expiration of this certificate, NMIJ will notify the registered customer. 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 11, 2017 The description on "Precautions for Handling" was added.

Jan. 24, 2019: The description on "Mutual Recognition Arrangement under Meter Convention" was added.

Sep. 19, 2019 The description in "Expiration of Certification" was changed to "one year from the date of shipment."