



CERTIFIED REFERENCE MATERIAL CERTIFICATE OF ANALYSIS

Report ID: M924.2016.01

Compound Name: **(-)-Ephedrine hydrochloride**

Collection Number: M924

Chemical Formula: C₁₀H₁₅NO.HCl

CAS Number: 50-98-6

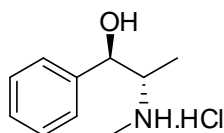
Structure:

Description: White solid

Batch Number: 06-D-01

Molecular Weight: 201.7 (HCl), 165.2 (base)

Release date: February 2006



Synonyms: L-Ephedrine hydrochloride;
(1R, 2S)-(-)-2-Methylamino-1-phenyl-propan-1-ol;
(1R, 2S)-(-)-Ephedrine hydrochloride;
L- α -[1-(Methylamino)ethyl] benzyl alcohol hydrochloride

Purity (mass fraction): 99.7 \pm 0.7% (95% coverage interval)

The purity value was obtained from a combination of traditional analytical techniques by subtraction from 100% of total impurities by GC-FID, thermogravimetric analysis, Karl Fischer analysis and ¹H NMR spectroscopy. Supporting evidence is provided by elemental microanalysis.

GC-FID: Instrument: Agilent 6890 or Varian CP3800
Column: HP-1 or VF-1MS, 30 m \times 0.32 mm I.D. \times 0.25 μ m
Program: 60 $^{\circ}$ C (1 min), 15 $^{\circ}$ C/min to 165 $^{\circ}$ C, 30 $^{\circ}$ C/min to 300 $^{\circ}$ C (3 min)
Injector: 250 $^{\circ}$ C Detector Temp: 320 $^{\circ}$ C
Carrier: Helium Split ratio: 20/1
Relative peak area response of main component:
Initial analysis: Mean = 99.8%, s = 0.01% (10 sub samples in duplicate, January 2006)
Re-analysis: Mean = 99.8%, s = 0.01% (5 sub samples in duplicate, January 2009)
Re-analysis: Mean = 99.8%, s = 0.01% (5 sub samples in duplicate, December 2016)

Thermogravimetric analysis: Initial volatile content < 0.1% (January 2006 and January 2007)
Non-volatile content not determined

Karl Fischer analysis: Moisture content < 0.2% mass fraction. (January 2009 and 2012)
Moisture content < 0.1% mass fraction. (November 2016)

Expiration of certification

The property values are valid till 13th December 2021, i.e. five years from the date of re-certification provided the **unopened** material is handled and stored in accordance with the recommendations below. The material as issued in the unopened container and stored as recommended below should be suitable for use beyond this date, subject to confirmation of batch stability from the issuing body.

The expiry date/shelf life does not apply to sample bottles that have been opened. In such cases it is recommended that the end-user conduct their own in-house stability trials.

The long-term stability of the compound in solution has not been examined.

This material has demonstrated stability over a minimum period of five years. The measurement uncertainty at the 95% coverage interval includes a stability component which has been estimated from annual stability trials.

Homogeneity assessment

The homogeneity of the material was assessed using purity assay by GC-FID on ten randomly selected 1-2 mg sub samples of the material. The material was judged to be sufficiently homogeneous at this level of sampling as the variation in analysis results between samples was not significantly different at a 95% confidence level from that observed on repeat analysis of the same sample.

Metrological traceability

The certified purity value is traceable to the SI unit for mass (kg) through Australian national standards via balance calibration. The purity was derived by subtraction of the mass of impurities from the mass of the reference material. Organic purity is traceable to the SI-derived coherent unit one through chromatographic separation and response factor determination of individual components. Volatile and non-volatile residue content is directly traceable to mass through use of Karl Fischer and thermogravimetric analysis.

Recommended storage

When not in use this material should be stored at or below 25 °C in a closed container in a dry, dark area.

Intended use

For *in vitro* laboratory analysis only.

Caution

Treat as hazardous substance. Use appropriate work practices when handling to avoid skin or eye contact, ingestion or inhalation of dust.

Legal notice

Neither NMI nor any person acting on NMI's behalf assumes any liability with respect to the use of, or for damages resulting from the use of, this reference material or the information contained in this certificate.

Authorised by:

S. R. Davies

Dr Stephen R. Davies,
Team Leader,
Chemical Reference Materials, NMI.
Dated: 4 January, 2017.

Characterisation data and property values specified in this report supersede those in all reports issued prior to 4th January 2017.