Dr. Ehrenstorfer

Reference Materials for Residue Analysis

Certificate of Analysis

ISO Guide 34 Reference Material

Product Identification

Article Code: DRE-C11555000
Article Name: Chlorpheniramine maleate
Formula: C16H19ClN2 · C4H4O4
Mol. Weight: 390.86
CAS No.: 113-92-8

Lot Number: G138191
Expiry Date: 03.12.2021
Storage Temperature: 20°C ± 4°C

Storage and handling: The RM should be stored in the original sealed bottle at the temperatur given above. After use the bottle should be tightly closed and protected from moisture and light. The expiry date is valid for original sealed bottles under recommended storage conditions only.

Purity:	99.55% (g/g)
Expanded Uncertainty U=	0.31% (g/g)

The uncertainty of this standard is calculated in accordance with the ISO Guide 34 and EURACHEM/CITAC Guide - Quantifying Uncertainty in Analytical Measurement, Second Edition. The expanded uncertainty is U(exp) = u(RM) x k, where k is the coverage factor at the 95% confidence level (k=2). Uncertainty u(RM) is based on the combination of the uncertainties associated with each individual operation involved in the analysis of the product: $u(RM) = \sqrt{u(char)^2 + u(bb)^2 + u(lts)^2 + u(sts)^2}$; u(char) is the uncertainty of purity determination; u(bb) uncertainty of homogeneity test; u(lts) uncertainty of stability test long-term; u(sts) uncertainty of stability test short-term. u(lts) and u(sts) are not included in the calculation as the stability statement is based on real evidence opposed to simulation.
Minimum sample: 1 mg is recommended as the minimal sample amount. If less material is used, it is recommended to increase the certified uncertainty by a factor of two for half sample and a factor of four for a quarter of sample.
Intended use: Use this RM as calibrant for chromatography or any other analytical technique.

Analytical Data

Traceability of chromatography: To the International System of Units (SI).

Intrument:	HPLC/DAD+MS	Method Details
Detection:	DAD+MS	Acetonitrile:Water 4:1
Column:	ReproSil 100 C18 5 µm 250 x 3 mm	
Inj.-Vol.:	10 µl	
Flow:	0.5 ml/min	
Ret.Time:	1.63 min	

Comment
Traceability: The balances used are calibrated with weights traceable to the national standards (DKD).
Calibrated class A glassware is used for volumetric measurements.
Certificate Revision 1
Water Content: 0.04% (g/g) by Karl-Fischer-Titration (U(exp) = 0.07% (g/g)).

Identity: EA, NMR, RT, IR, UV, MS

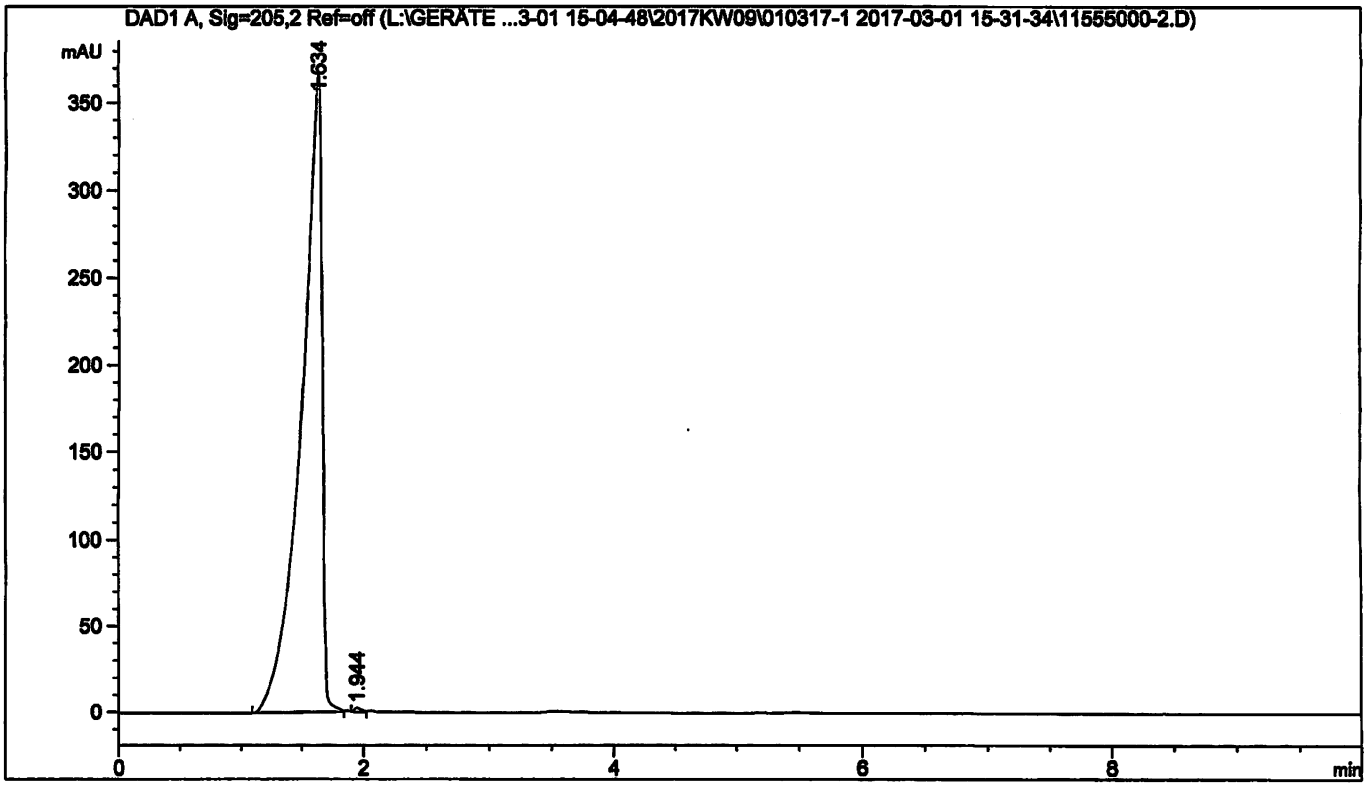
Certified on: 26.05.2017
Certified by: Dr. K.Wörmann

The LGC Labor GmbH, accreditated by DAkkS as indicated by the accreditation number D-RM-19883-01 & D-PL-19883-01, has shown competence based on ISO Guide 34:2009 with relevant parts of DIN EN ISO/IEC 17025:2005 for production of certified reference materials in form of organic pure substances and in form of single and multi-component solutions of organic pure substances.

LGC Labor GmbH - Bgm.-Schlosser-Straße 6A - 86199 Augsburg - Germany
Phone +49 821 906080 - Fax +49 821 9060888 - augsburg.inquiry@lgcgroup.com

Acq. Operator : DAD3_Admin Seq. Line : 39
Acq. Instrument : DAD3 Location : 50
Injection Date : 01.03.2017 21:07:17 Inj : 1
Inj Volume : 10.000 µl
Acq. Method : C:\Chem32\1\DATA\2017KW09\010317-1 2017-03-01 15-04-48\2017KW09\010317-1 2017-03-01 15-31-34\41MSNEG.M
Last changed : 08.11.2016 07:36:57 by DAD3_Admin
Analysis Method : L:\GERÄTE BACKUP\DAD3\METHODS\41MSNEG.M
Last changed : 26.02.2015 17:11:54 by DAD3_Admin
Method Info : Acetonitrile : Water 4:1

Sample Info : Chlorpheniramine maleate



Area Percent Report

Sorted By : Retention Time
Multiplier : 1.0000
Dilution : 1.0000
Use Multiplier & Dilution Factor with ISTDs

Signal 1: DAD1 A, Sig=205,2 Ref=off

Peak #	RetTime [min]	Sig	Type	Area [mAU*s]	Height [mAU]	Area %
1	1.634	1	BV	4214.52051	367.44992	99.8078
2	1.944	1	BV	8.11684	2.06183	0.1922
Totals :				4222.63735	369.51175	

*** End of Report ***