

Gravimetric Certificate

Dr. Ehrenstorfer



Product Identification

17940000 Warfarin
Formula C₁₉H₁₆O₄
Mol. Weight 308.4
CAS No. 81-81-2

Reference Materials for Residue Analysis

Expiry Date 01.02.2019
Lot Number 94421AL
Store at 20°C in the dark

Please note: The expiry date is valid under recommended storage conditions only.

Gravimetric Data				
Product Name		Conc. (mg/l)	Purity %	Weight (mg)
Warfarin		100.000	99.0	3.034
Solvent Information				
Solvent		Lot No.	Exact Quantity (ml)	
Acetonitrile		150108104	30.00	
Traceability Data				
17940000 40611		neat product		
17940000 94421AL		100.000 mg/l		
Analytical Data				
Detection: HPLC/DAD		Method Details:		
Column: ReproSil 100 C18 5µ 250x3		Acetonitrile:H2O+0,5% H3PO4 4:1		
Inj.-Vol.: 10.00 µl				
Flow: 1.0 ml/min				
Ret.-Time: 1.75 min.				
Identity check UV, RT				
Comment				
The uncertainty/tolerance of this standard is +/- 2.0 %, calculated in accordance with the EURACHEM/CITAC Guide - Quantifying Uncertainty in Analytical Measurement - Second Edition. The uncertainty given is the expanded combined uncertainty and represents an estimated standard deviation equal to the positive square root of the total variance of the uncertainty of components. The expanded uncertainty is U w hich is Uc(y)*K, where K is the coverage factor at the 95% confidence level (K=2). The expanded uncertainty is based on the combination of uncertainties associated with each individual operation involved in the preparation of this product.				

Certified on 01.02.2016

by M. Beck

The Laboratory LGC Labor GmbH is accredited 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 organic pure substances.

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The warranty for this product is limited to the purchasing price of this product.

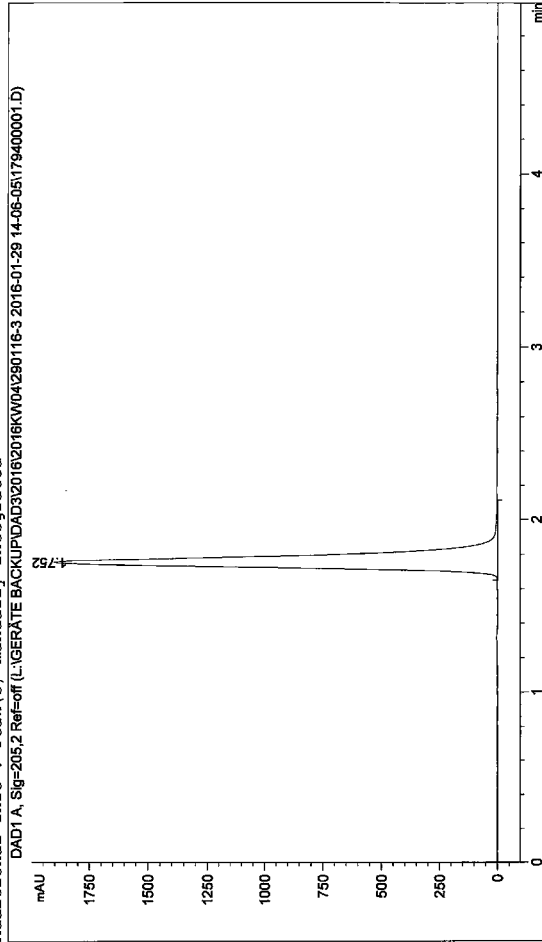
01.02 17

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Acq. Operator	: DAD3_Admin	Seq. Line	: 103
Acq. Instrument	: DAD3	Location	: Vial 18
Injection Date	: 30.01.2016 12:47:40	Inj	: 1
		Inj Volume	: 10.000 µl
Acq. Method	: C:\CHEM32\1\DATA\2016KW04\290116-3 2016-01-29 14-06-05\41PK.M		
Last changed	: 10.11.2015 09:18:37 by DAD3_Admin		
Analysis Method	: L:\GERÄTE BACKUP\AD3\METHODS\41PK.M		
Last changed	: 10.11.2015 09:18:37 by DAD3_Admin		
Method Info	: Acetonitrile Water 4:1 + 0.5 % H3PO4		

Sample Info : Warfarin

Additional Info : Peak(s) manually integrated



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	1.752	1	VB	8771.38965	1907.86414	100.0000

Totals : 8771.38965 1907.86414

*** End of Report ***

Dr. Ehrenstorfer

Reference Materials for
Residue Analysis

1. Application:

This standard solution is designed for calibration or recalibration of chromatographic systems for the determination of the specified chemical compounds concerning identity and quantification. The product can also be used as reference material for interlaboratory studies to validate analytical procedures.

2. Raw material:

All raw materials used to prepare this standard solution are of the highest purity. After our production process each material is checked by several of the following methods, if applicable: UV-, IR-Spectroscopy, Elemental analysis, chromatographical properties (GC/FID, GC/ECD, GC/MSD, HPLC/DAD, HPLC/MSD, TLC) and physical properties (phase, colour, odor, melting point) and Karl-Fischer for detection of traces of water.

3. Manufacturing

Prior to the production for each standard solution we calculate the necessary weight of the neat material, compensate the difference of the purity of the compound to 100%. We use an electronic scale capable of weighing to 0.000001 g with a built in automatic calibration function, which is executed minimum once a week. Once a month the balance is calibrated with weights complying with the OIML-IP-20 design requirements and traceable to the national prototype of the Physikalisch-Technische Bundesanstalt Braunschweig, the German office of weights and measurements. Every year the balance is calibrated by the manufacturer service technician. This company is also certified by the DQS following ISO9001. All steps are documented conform to ISO 9001 requirements. The single components are weighed and filled into volumetric flask (class A glassware) with the exact quantity of solvent as indicated on the certificate. Solvents are stored and handled in special rooms, which have the constant ambient temperature required from the manufacturer of the volumetric equipment. The tolerance of the weighing procedure and the dilution error adds to a maximum of +/- 1.0 %.

4. Packaging and Storage:

The final formulation was packaged in amber glass ampoules and then sealed to prevent photodegradation and evaporation. Every reference material is stored under controlled condition. One sample of each lot is kept according GLP rules to allow a recheck of the specific lot even years after the last item was sold.

5. Stability:

In regular intervals each lot is checked for stability. We guarantee the stability of the solution until the date of expiry given on the Gravimetric Certificate. In case, that the tests show a degradation within the shelf life period, the customer will be notified. We recommend to store the ampoules in the dark at 20 °C +/- 4 °C

6. Gravimetric Certificate:

The documentation gives all the data of the production process with all the information necessary for traceability of each lot. Following GLP rules you are obliged to note the used product, lot number of the product, purity, exact weight/quantity of the product, name of the solvent, lot number of the solvent, exact quantity of the solvent, date of production, date of expiry and signature of the person in charge. Copies have to be authorized by stamp, signature of the person in charge according to your quality management handbook and date of authorization.

7. Analytical Quality Control

The summary of the quality control procedure is documented in the separate Certificate of Analysis. Our company holds the Quality System Certificate DQS-Reg No.: 002874 QM08 for the standard from the ISO 9001 / EN 29000 series and the scope as specified. The audit performed by the DQS has verified, that our quality system fulfills the requirements of DIN ISO 9001. The company is accredited by DAkkS as indicated by the Accreditation Number D-RM-19883-01 and D-PL-19883-01 has shown competence based on ISO Guide 34. Accredited 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 organic pure substances.