Certificate of Analysis

Dr. Ehrenstorfer

Reference Materials for Residue Analysis

Product Identification

10242500 Amoxicillin trihydrate

CA 6-((Amino(4-hydroxyphenyl)acetyl)amino)-3,3-dimethyl-7-oxo-4-thia-1-

IUPAC

Formula C16H19N3O5S 3H2O

Mol.Weight 419.4

CAS No. 61336-70-7

Expiry Date 21.03.2016

Lot Number 20323

Store at 20 °C ±4 °C

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

Toxicological Data

R Code

S Code

LD50 (Rats female/male in mg/kg) N/A

Physical Data

Phase crystalline solid

Color colourless

Melt.Range dec. 184.8 °C

Vapour pressure N/A at °C

Solubility in water N/A g/l at °C

Boiling Range (lit.)

Analytical Data

Detection: HPLC/DAD

Column: ReproSil 100 C18 5µ 250x3

Inj.-Vol.: 10.00 µl

Flow: 1.0 ml/min

Ret.-Time: **1.18 min.**

Method Details:

Acetonitrile:H2O 1:9

Identity: UV, RT

Comment purity was confirmed by external standard method

Water Content 15.3 % Determined by Karl-Fischer Titration

Det. Purity 99.5 % Tolerance/Uncertainty +/- 0.5 %

The uncertainty/tolerance of this standard is 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 which 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 29.01.2013

by P. Feuerriegel

The Laboratory Labor Dr. Ehrenstorfer-Schäfers is accreditated by DAkkS as indicated by the Accreditation Number D-RM-14174-01 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.

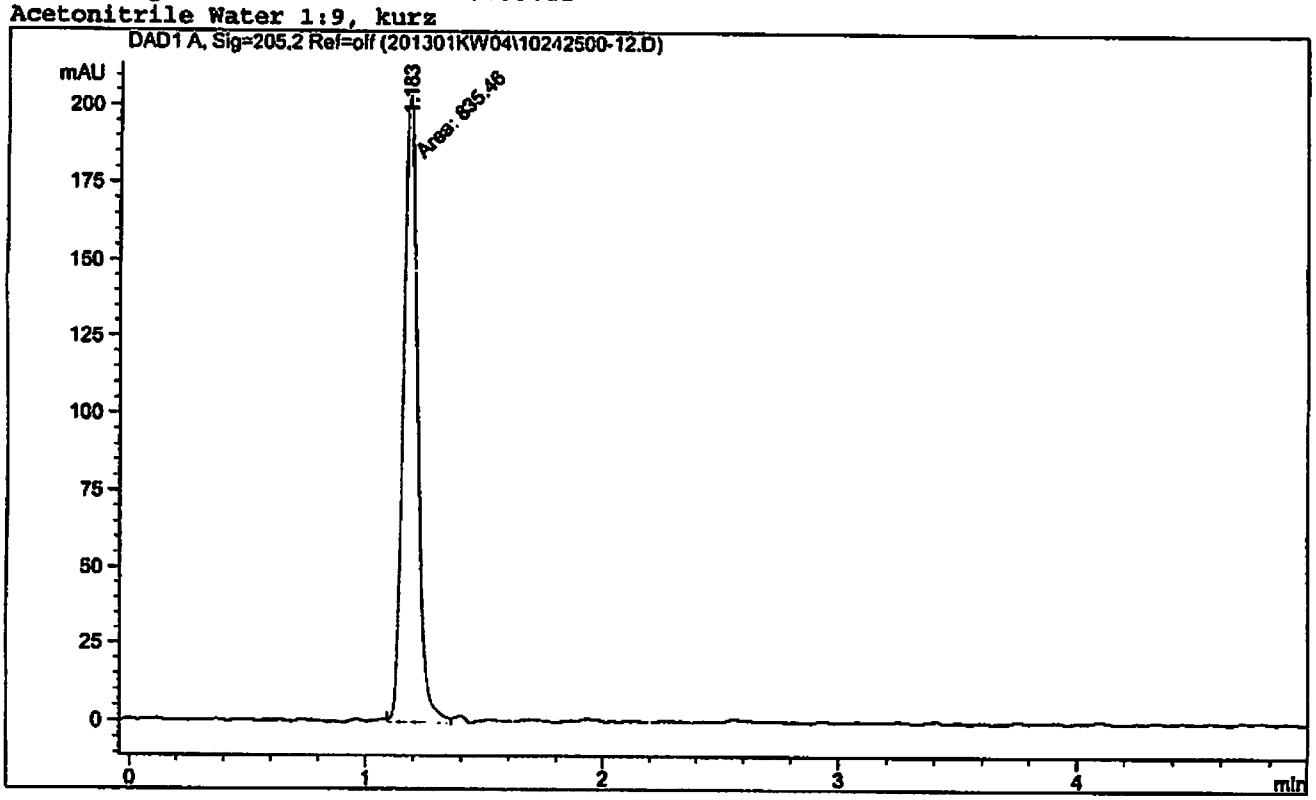
Data File D:\CHEM32\1\DATA\201301KW04\10242500-12.D
Sample Name: 30125WA 20323

Amoxicillin trihydrate
(Sondereluent A: AL, B: 250mL KH2PO4 (0,2 mol/l)

25.01.13

Injection Date	: 24.01.2013 11:11:55	Seq. Line	: 3
Sample Name	: 30125WA 20323	Location	: Vial 2
Acq. Operator	: DAD1_Admin	Inj	: 2
Acq. Instrument	: Instrument 1	Inj Volume	: 10 µl
Different Inj Volume from Sequence !		Actual Inj Volume	: 3 µl
Method	: C:\CHEM32\1\METHODS\19K.M		
Last changed	: 03.05.2012 13:33:11		

Acetonitrile Water 1:9, kurz



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	1.183	1	FM	835.46033	204.70482	100.0000
Totals :				835.46033	204.70482	

*** End of Report ***