

Certificate of Analysis

Dr. Ehrenstorfer



Product Identification

10386000 Azithromycin dihydrate

CA 1-Oxa-6-azacyclopentadecan-15-one,13-[[2,6-dideoxy-3-C-methyl-3-O-methyl- α -L-ribo-

IUPAC 1-Oxa-6-azacyclopentadecan-15-one,13-[[2,6-dideoxy-3-C-methyl-3-O-methyl- α -L-ribo-

Formula C₃₈H₇₂N₂O₁₂ x2H₂O

Mol.Weight 784.98

CAS No. 117772-70-0

Reference Materials for
Residue Analysis

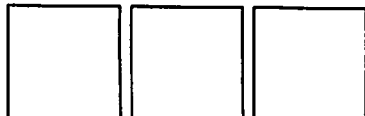
Expiry Date 27.02.2018

Lot Number 20626

Store at 20 °C \pm 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) >2000

Physical Data

Phase crystalline solid

Vapour pressure N/A at °C

Color colourless

Solubility in water N/A g/l at °C

Melt.Range 127 °C

Boiling Range (lit.)

Analytical Data

Detection: LC/MSD

Method Details:

Column: ReproSil 100 C18 5 μ 250x3

Acetonitrile:H₂O+0,15% Formic acid 1:1

Inj.-Vol.: 10.00 μ l

Flow: 0.5 ml/min

Ret.-Time: 4.22 min.

Identity: MS, RT

Comment purity was confirmed by external standard method

Water Content 4.8 %

Determined by Karl-Fischer Titration

Det. Purity 97.0 %

Tolerance/Uncertainty +/- 1.0 %

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 $U_c(y) \cdot K$, 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 27.02.2013

by P. Feuerriegel

The Laboratory Labor Dr. Ehrenstorfer-Schäfers is accredited 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.

Labor Dr. Ehrenstorfer-Schäfers · Bgm.-Schlosser-Str. 6 A · 86199 Augsburg · Germany

Phone +49 821 906080 · Fax +49 821 9060888 · info@analytical-standards.com

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

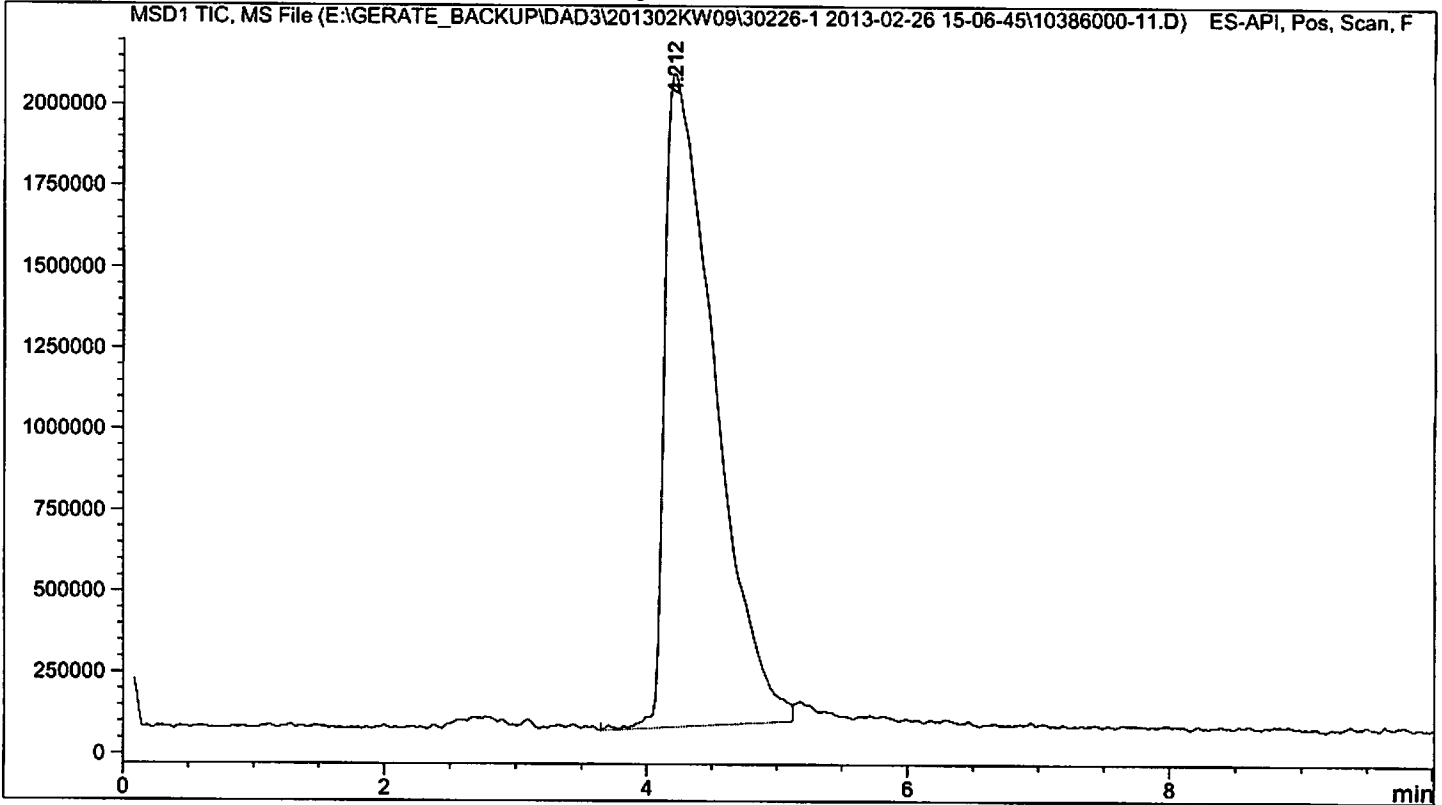
27.2.13

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Acq. Operator   : DAD3                               Seq. Line :    7
Acq. Instrument : DAD3                               Location  : Vial 8
Injection Date  : 26.02.2013 18:10:25                Inj       :    1
                                                    Inj Volume: 10.000 µl

Acq. Method     : C:\CHEM32\1\DATA\201302KW09\30226-1 2013-02-26 15-06-45\11MS_S2.M
Last changed    : 30.07.2012 11:49:14 by DAD3
Analysis Method : E:\GERÄTE_BACKUP\DAD2\METHODS\11MS_S2.M
Last changed    : 27.02.2013 09:26:34
                  (modified after loading)
Method Info     : Acetonitrile : Water 1:1 + 0.15% Formic acid

Sample Info     : Azithromycin dihydrate (Column: RepronilPur CN, 250 x 3
                  mm, 5 µm)
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Additional Info : Peak(s) manually integrated



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

Signal 1: MSD1 TIC, MS File

Peak #	RetTime [min]	Sig	Type	Area	Height	Area %
1	4.212	1	BV	5.38131e7	2.02421e6	100.0000

Totals : 5.38131e7 2.02421e6