

# Certificate of Analysis

Dr. Ehrenstorfer

Reference Materials for  
Residue Analysis

## Product Identification

10386000 Azithromycin dihydrate

CA 1-Oxa-6-azacyclopentadecan-15-one,13-[(2,6-dideoxy-3-C-methyl-3-O-methyl- $\alpha$ -L-ribo-

IUPAC 1-Oxa-6-azacyclopentadecan-15-one,13-[(2,6-dideoxy-3-C-methyl-3-O-methyl- $\alpha$ -L-ribo-

Formula C<sub>38</sub>H<sub>72</sub>N<sub>2</sub>O<sub>12</sub> x2H<sub>2</sub>O

Mol.Weight 784.98

CAS No. 117772-70-0

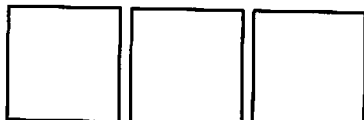
Expiry Date 27.02.2018

Lot Number 20620

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

Boiling Range (lit.)

## Analytical Data

Detection: LC/MSD

Method Details:

Column: Reprosil 100 C18 5 $\mu$  250x3

Acetonitrile:H<sub>2</sub>O+0,15% Formic acid 1:1

Inj.-Vol.: 10.00  $\mu$ l

Flow: 0.5 ml/min

Ret.-Time: 4.23 min.

Identity: RT, MS

Comment Purity was confirmed by external standard method  
Column: Reprosil pur CN 5 $\mu$ m 250\*3mm

Water Content

Determined by Karl-Fischer Titration

Det. Purity 98.0 %

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  $U_c(y) \cdot K$ , 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



REF.NO: 2014-01

The Laboratory Labor Dr. Ehrenstorfer-Schäfers is accredited by DGA as indicated by the Accreditation Certificate DGA-PL-4536.00 based on DIN EN ISO/IEC 17025:2005 for the weighing of amounts of substances for the preparation of standard solutions.

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



DGA-PL-4536.00

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Acq. Operator	: [BSB1]DAD3	Seq. Line	: 6
Acq. Instrument	: DAD3	Location	: Vial 7
Injection Date	: 26.02.2013 17:48:01	Inj	: 1
		Inj Volume	: 10.000 µl

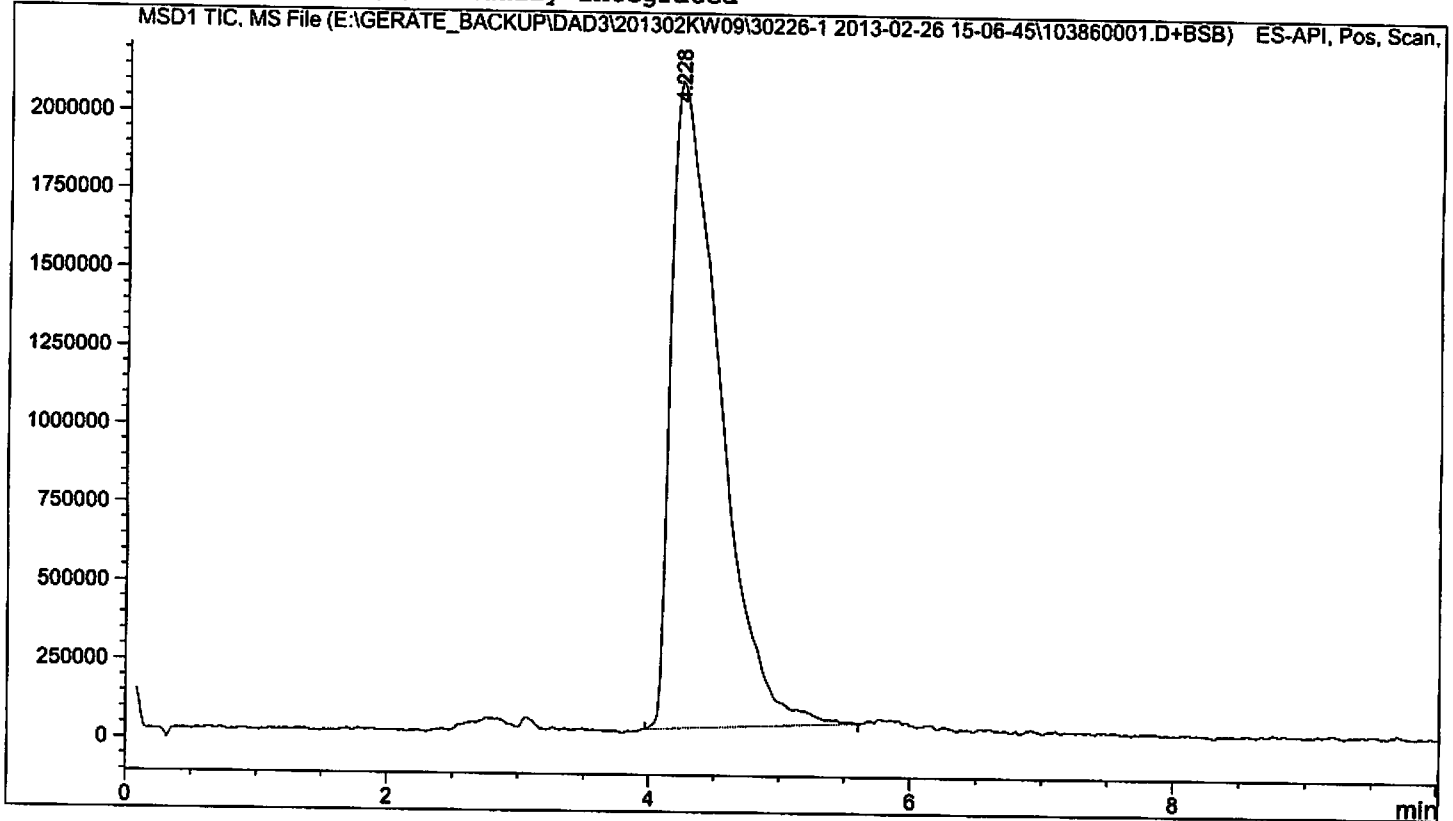
Acq. Method : C:\CHEM32\1\DATA\201302KW09\30226-1 2013-02-26 15-06-45\11MS\_S2.M  
Last changed : 30.07.2012 11:49:14 by DAD3  
Analysis Method : E:\GERÄTE\_BACKUP\DAD2\METHODS\11MS\_S2.M  
Last changed : 27.02.2013 09:26:34  
(modified after loading)

Method Info : Acetonitrile : Water 1:1 + 0.15% Formic acid

Sample Info : Azithromycin dihydrate (Column: ReprosilPur CN, 250 x 3 mm, 5 µm)

27.2.13

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	4.228	1	BB	5.39490e7	2.07032e6	100.0000

Totals : 5.39490e7 2.07032e6