

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-a-L-ribo-

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

Formula C₃₈H₇₂N₂O₁₂ x2H₂O

Mol.Weight 784.98

CAS No. 117772-70-0

Reference Materials for Residue Analysis

Expiry Date 22.02.2022

Lot Number 127612

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) >2000

Physical Data

Phase crystalline solid

Color colourless

Melt.Range 125,5 °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: 3.73 min.

Identity: RT, UV, MS, EA

Comment Purity was confirmed by elemental analysis.

Eluent : 90% Methanol / 10% Phosphate Puffer (pH = 8.0)

No chromatogram available.

Water Content 4.5 % Determined by Karl-Fischer Titration

Det. Purity 99.0 % 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 $Uc(y) \cdot K$, 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 22.02.2017

by Dr. K. Wörmann

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.