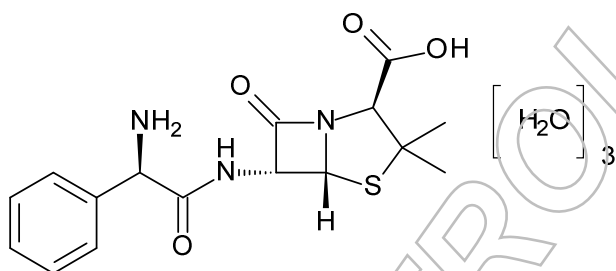




Certificate of Analysis

Reference Standard

Ampicillin Trihydrate



Molecular Formula: $C_{16}H_{19}N_3O_4S \cdot 3H_2O$
Molecular Weight: 403.45
CAS Number: 7177-48-2

Catalogue Number: LGCFOR0253.15
Lot Number: 56596
Long-term Storage: 2 to 8 °C, dark
Appearance: white solid
Melting Point: 197 °C (dec.)
Assay 'as is': 99.9 %

Date of shipment: **2016-May-20**

This certificate is valid for two years from the date of shipment provided the substance is stored under the recommended conditions unopened in the original container.

LGC Quality ISO 9001:2008
DQS 102448 QM08

LGC GmbH, Im Biotechnologiepark, TGZ II, D-14943 Luckenwalde, Germany

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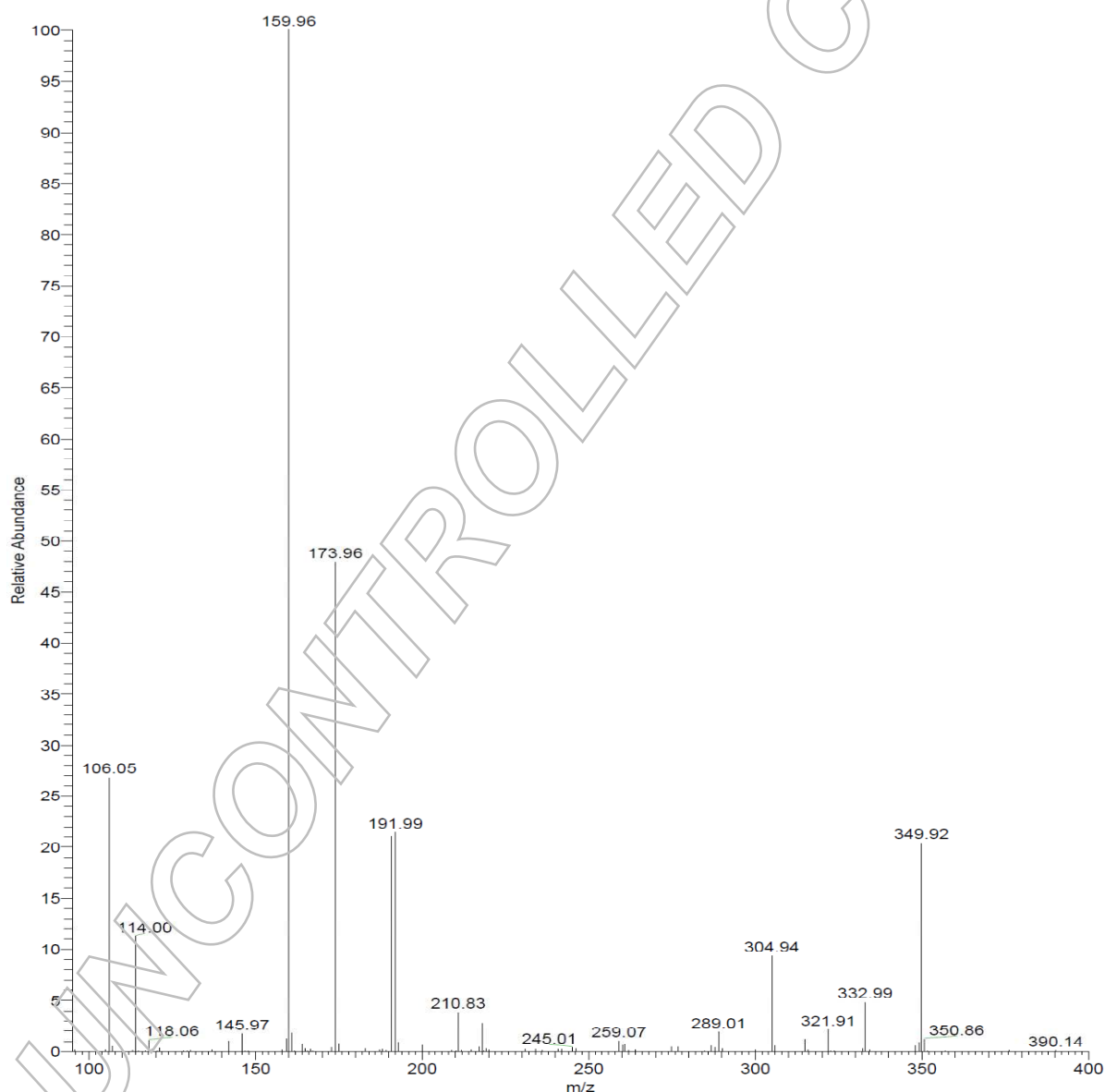


I. Identity

The identity of the reference substance was established by following analyses.

Ia. Mass Spectrum

Method: 4.5 kV ESI+; vaporization temperature: 200 °C

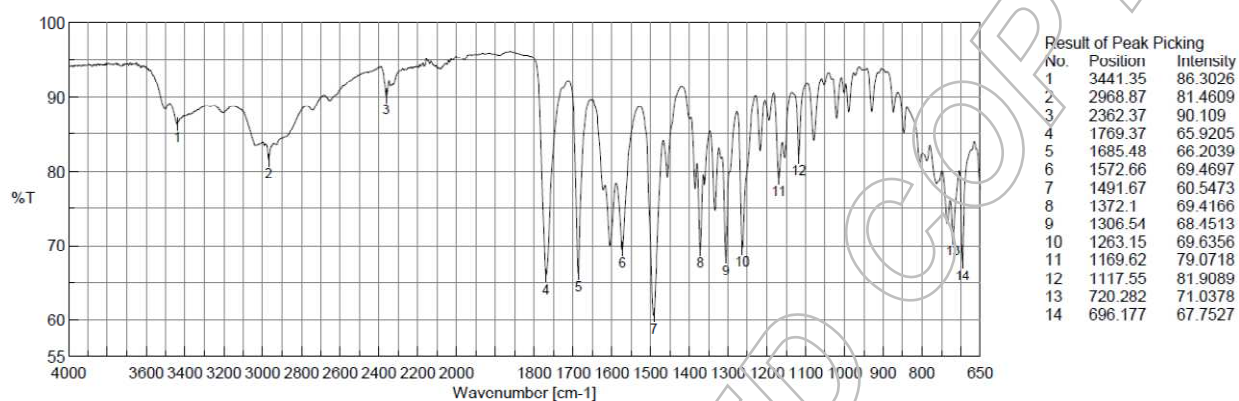


The signals of the mass spectrum and their interpretation are consistent with the structural formula.



Ib. IR Spectrum

Method: Attenuated Total Reflection Fourier Transform Infrared (ATR-FTIR) Spectroscopy



The signals of the IR spectrum and their interpretation are consistent with the structural formula.

II. Purity

Ila. High Performance Liquid Chromatography (HPLC)

The purity of the reference substance was analysed by high performance liquid chromatography (HPLC).

HPLC Conditions:

Column:

LiChrospher
60 RP-select B
5 µm, 125 x 4 mm

Conditions:

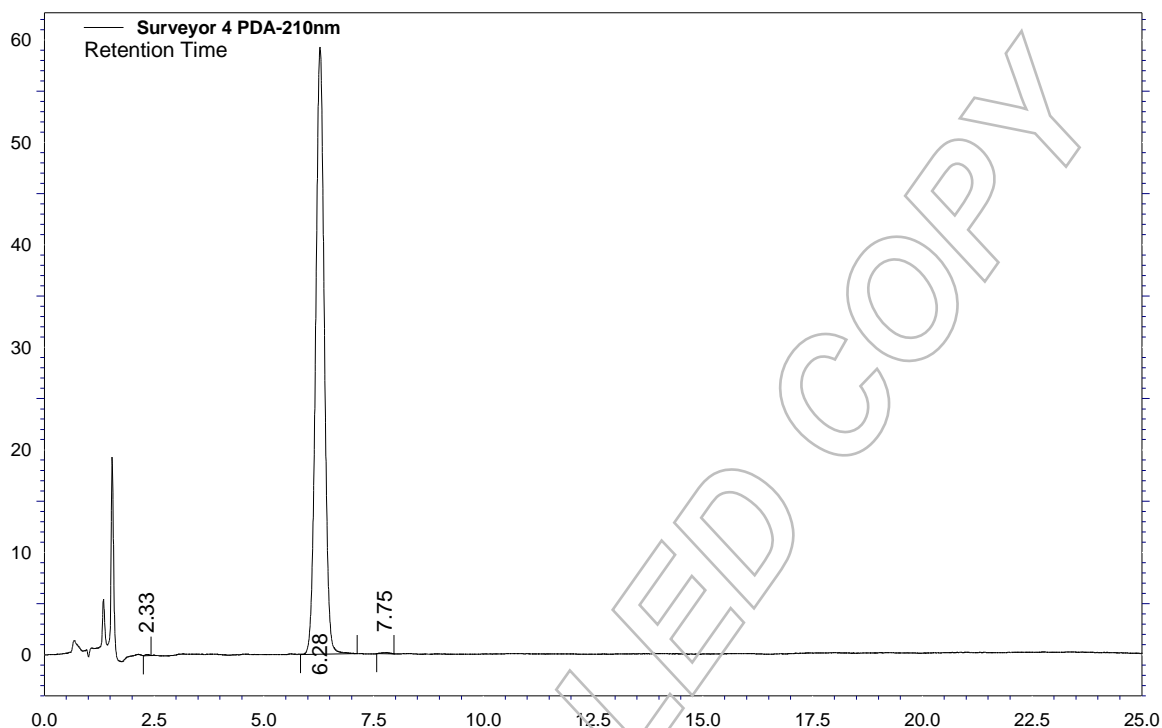
1.0 ml/min, 40 °C
NaH₂PO₄ pH 5.5/Acetonitrile 95/5 (v/v)

Detector:

DAD
210 nm

Injector:

Auto
2 µl; 0.05368 mg/ml in
Water/Acetonitrile 50/50 (v/v)



Area Percent Report - Sorted by Signal

Pk #	Retention Time	Area	Area %
1	2.33	608	0.07
2	6.28	810153	99.76
3	7.75	1353	0.17
Totals		812114	100.00

For the calculation the system peaks were ignored. The content of the analyte was determined as ratio of the peak area of the analyte and the cumulative areas of the purities, added up to 100 %.

Results:

Average	99.75 %
Number of results	n=6
Standard deviation	0.04 %



IIb. Water Content

Method: Karl Fischer titration

Determined value	13.28 %
Theoretical value	– 13.40 %
Content of excessive water	– 0.12 %

III. Final Result

Chromatographic purity (HPLC) 99.75 %

Water content – 0.12 %

Assay (100 % method)¹ 99.87 %

The assay is assessed to be 99.9 % 'as is'

The assay 'as is' is equivalent to the assay based on the not anhydrous and not dried substance respectively.

Release Date:

Luckenwalde, 2014-12-09

Dr. Sabine Schröder
Product Release

¹ The calculation of the 100 % method follows the formula:

$$\text{Assay (\%)} = (100 \% - \text{volatile contents}) * \frac{\text{Purity (\%)}}{100 \%}$$

Volatile contents are considered as absolute contributions, purity is considered as relative contribution.

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