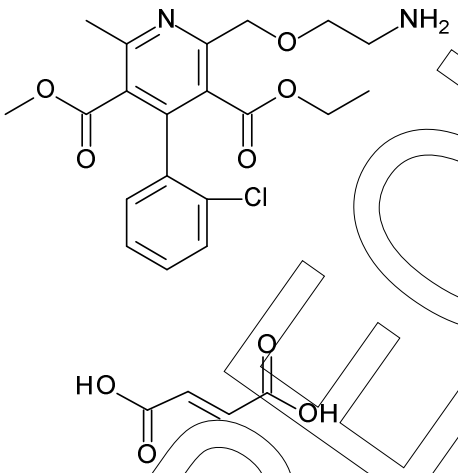
Certificate of Analysis

Reference Standard

3-Ethyl 5-Methyl 2-[(2-Aminoethoxy)methyl]-
4-(2-chlorophenyl)-6-methylpyridine-
3,5-dicarboxylate Fumarate



Molecular Formula:	$C_{20}H_{23}ClN_2O_5 \cdot C_4H_4O_4$
Molecular Weight:	522.93
CAS Number:	not listed

Catalogue Number:	LGCFOR0383.12
Lot Number:	86882
Long-term Storage:	2 to 8 °C, dark
Appearance:	white solid
Melting Point:	142 °C
Assay ‘as is’:	97.3 %

Date of shipment: **2020-November-30**

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

LoGiCal® produced by LGC

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

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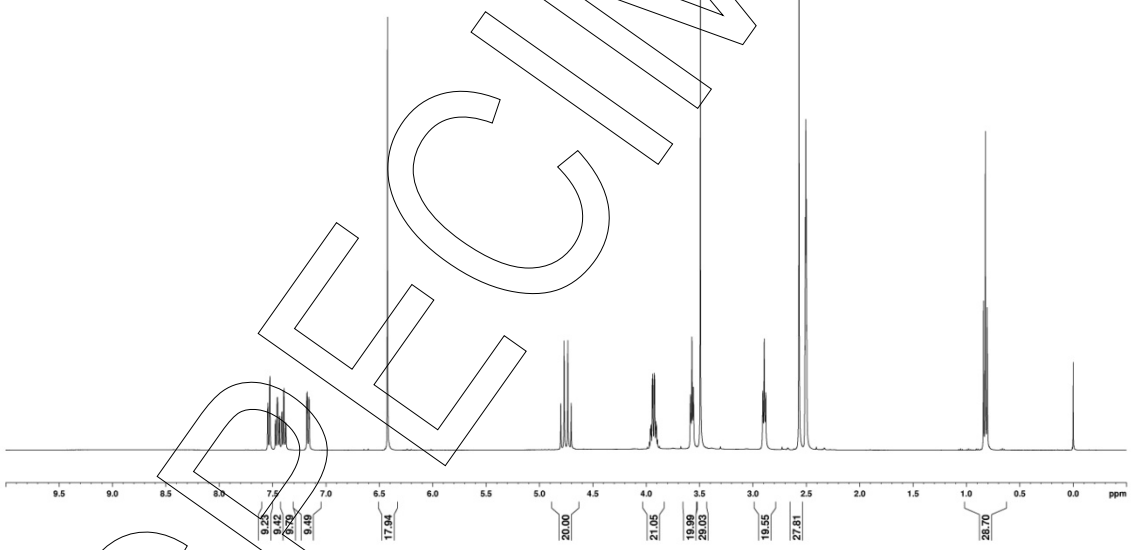
I. Identity

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

Ia. ^{1}H-NMR Spectrum

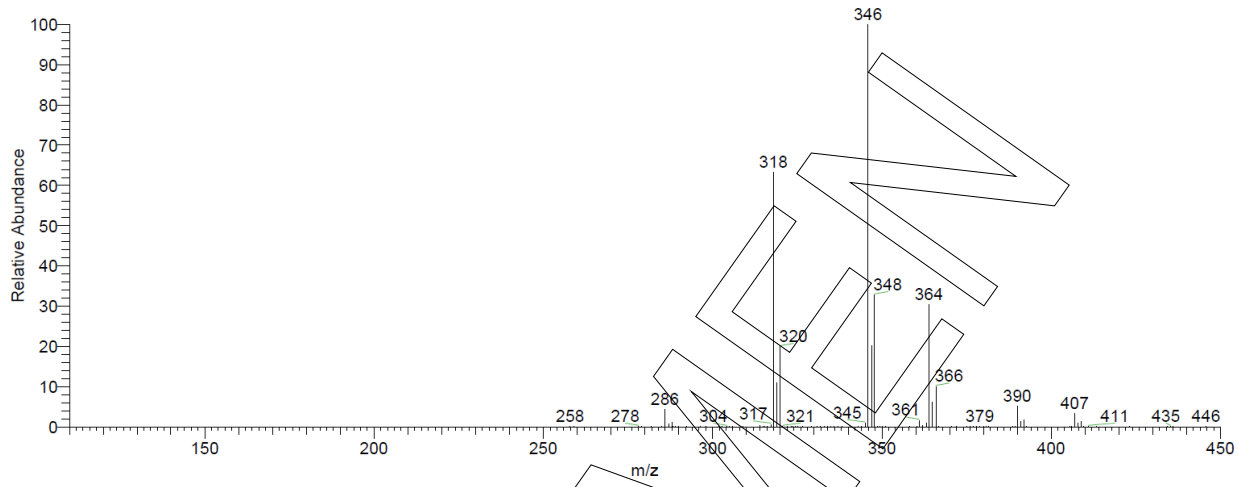
Conditions: 400 MHz, DMSO-d_6



The structure is confirmed by the signals of the spectrum and their interpretation.

Ib. Mass Spectrum

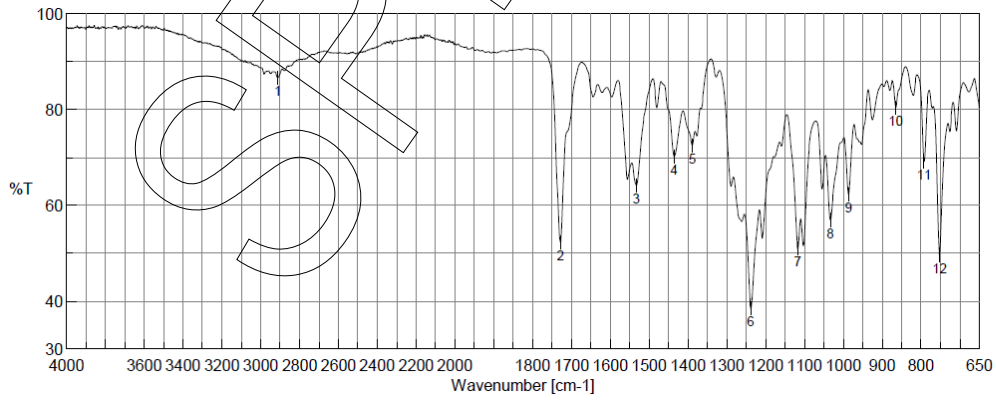
Method: 4.5 kV ESI+; vaporization temperature: 200 °C



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

Ic. IR Spectrum

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



Result of Peak Picking

No.	Position	Intensity
1	2912.95	86.5731
2	1728.87	52.2866
3	1533.13	64.1411
4	1435.74	70.1105
5	1388.5	72.4609
6	1238.08	38.4608
7	1116.58	50.8978
8	1033.66	56.8505
9	986.411	62.2277
10	864.917	80.3529
11	792.6	69.1224
12	752.102	49.6544

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

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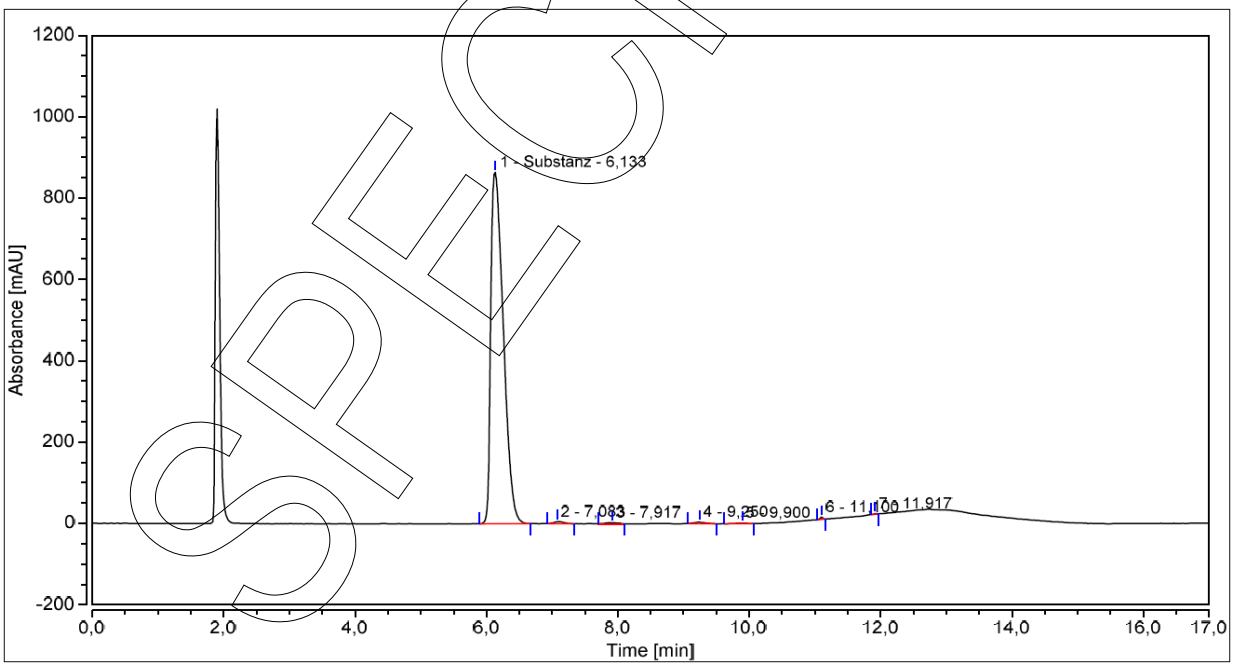
II. Purity

IIa. High Performance Liquid Chromatography (HPLC)

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

HPLC Conditions:

Column:	**Conditions:**	**Detector:**	**Injector:**
Hypersil Gold C18	1.0 ml/min, 40 °C	DAD	Auto
5 µm, 150 x 4.6 mm	0-7 min Water/Acetonitrile 72/28 7-10 min Water/Acetonitrile to 20/80 10-12 min Water/Acetonitrile to 72/28 12-17 min Water/Acetonitrile 72/28 (v/v); 0.1 % H_3PO_4	210 nm	5 µl; 0.2632 mg/ml in Water/Acetonitrile 50/50 (v/v)



Area Percent Report - Sorted by Signal

Pk #	Retention Time	Area	Area %
1	6.133	190.574	98.54
2	7.083	0.922	0.48
3	7.917	0.511	0.26
4	9.250	0.763	0.39
5	9.900	0.280	0.14
6	11.100	0.289	0.15
7	11.917	0.065	0.03
Totals		193.404	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	98.53 %
Number of results	n=3
Standard deviation	0.02 %

IIb. Water Content

Method: Karl Fischer titration

Results:

Average	1.29 %
Number of results	n=3
Standard deviation	0.05 %

IIc. Residual Solvents

Method: ^{1}H-NMR

No significant amounts of residual solvents were detected (< 0.05 %).

III. Final Result

Chromatographic purity (HPLC)	98.53 %
Water content	1.29 %
Residual solvents	No significant amounts of residual solvents were detected (< 0.05 %).
Assay (100 % method)[1]	97.26 %

The assay is assessed to be 97.3 % 'as is'

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

Release Date:

Luckenwalde, 2015-10-07

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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