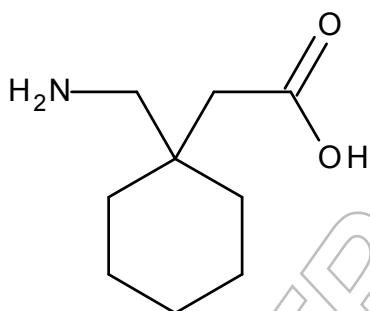




Certificate of Analysis

Reference Standard

Gabapentin



Molecular Formula: $C_9H_{17}NO_2$
Molecular Weight: 171.24
CAS Number: 60142-96-3

Catalogue Number: LGCFOR0684.00
Lot Number: 122015
Long-term Storage: 2 to 8 °C, dark
Appearance: white solid
Melting Point: 152 °C
Assay 'as is': 99.9 %

Date of shipment: **2017-January-25**

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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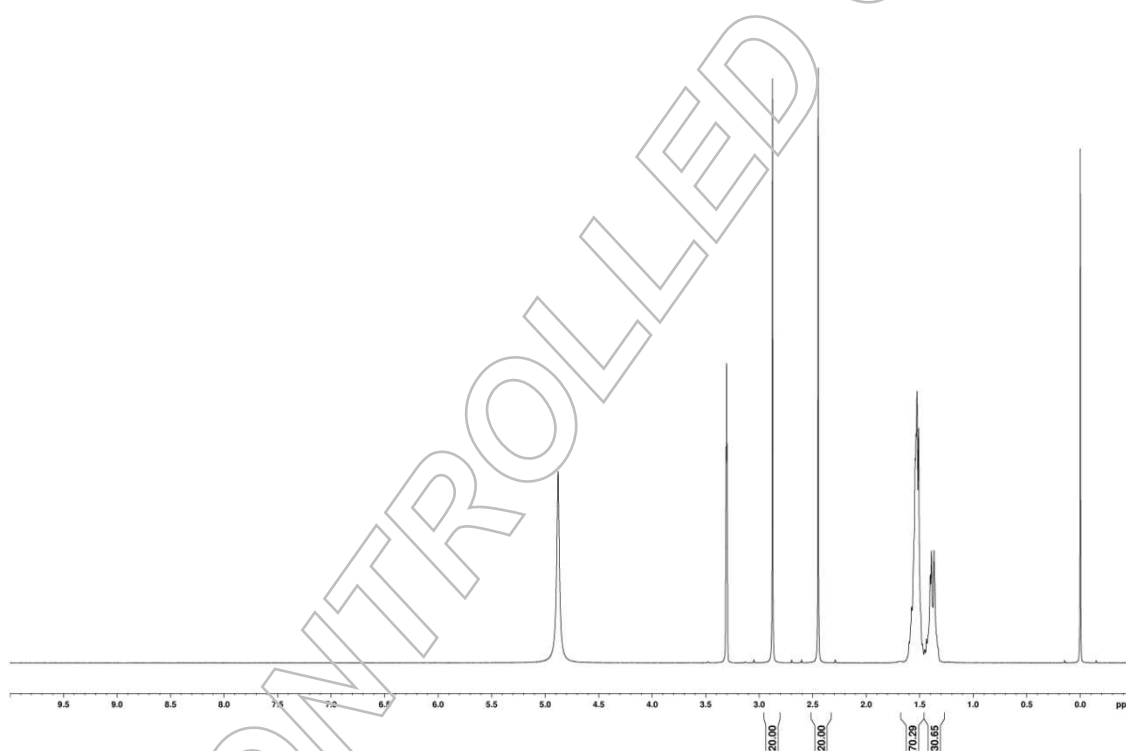


I. Identity

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

Ia. ^1H -NMR Spectrum

Conditions: 400 MHz, CD_3OD

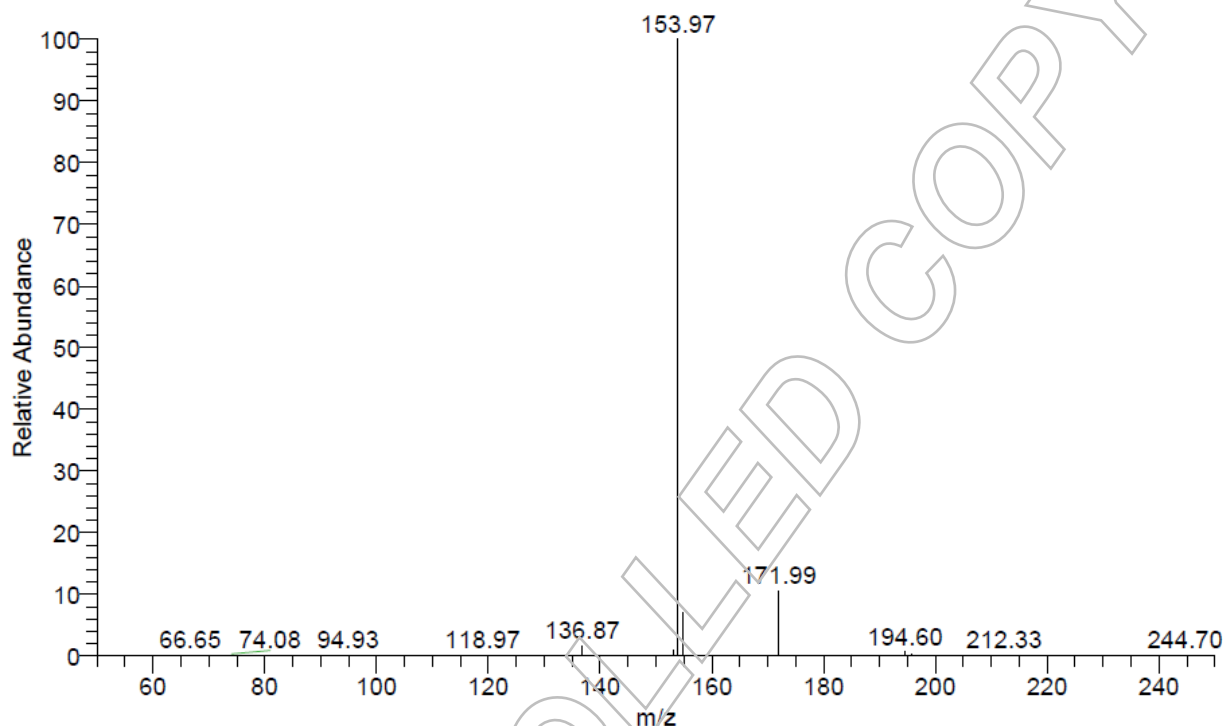


The structure is confirmed by the signals of the spectrum and their interpretation.



Ib. Mass Spectrum

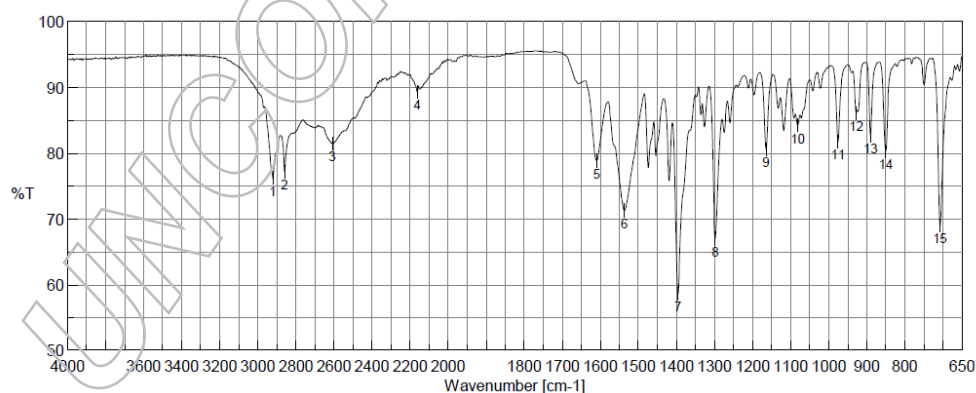
Method: 4.5 kV ESI+; vaporization temperature: 200 °C



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	2920.66	76.1643
2	2858.95	77.1838
3	2607.29	81.4546
4	2161.81	89.2458
5	1610.27	78.8357
6	1536.99	71.2639
7	1396.21	58.5679
8	1297.86	66.9609
9	1164.79	80.5721
10	1080.91	84.1772
11	975.804	81.6996
12	927.593	86.0494
13	889.987	82.7138
14	850.454	80.2666
15	707.747	68.984

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



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:

Luna C 18(2)
5 μ m, 250 x 4.6 mm

Conditions:

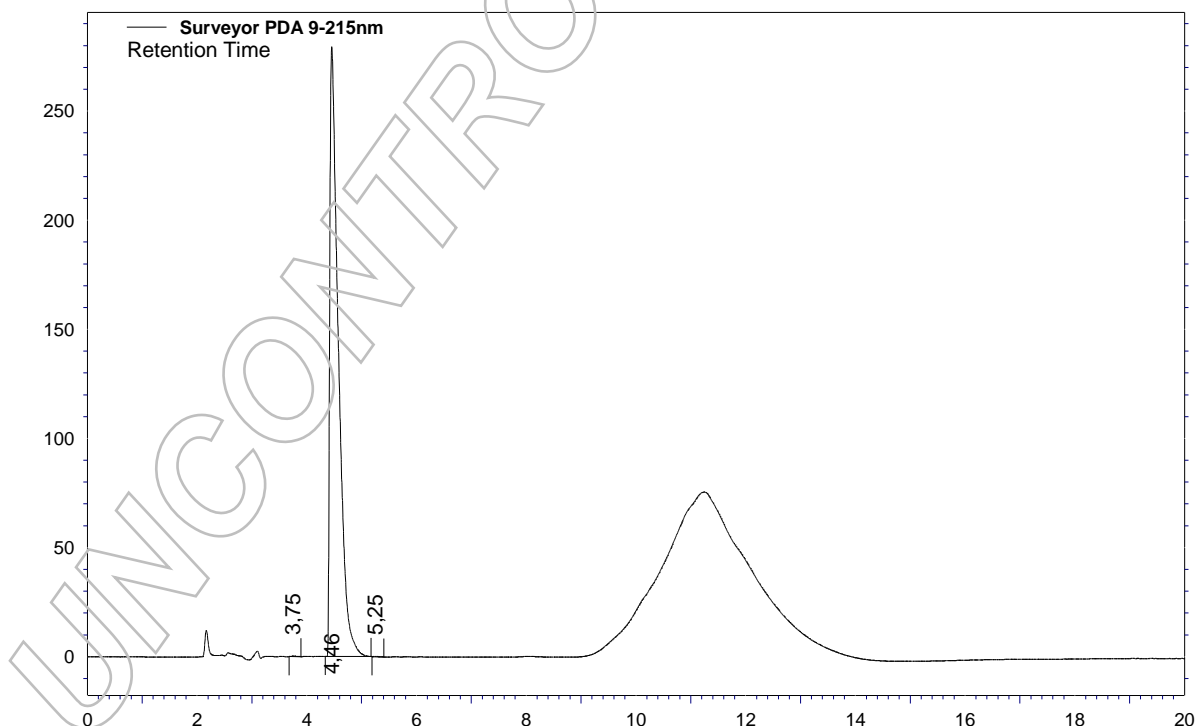
1.0 ml/min, 40 °C
Buffer solution: 0.58 g/l $\text{NH}_4\text{H}_2\text{PO}_4$ + 2.1 g/l
 NaClO_4 pH 1.8
0-5 min Buffer/Acetonitrile 76/24
5-8 min Buffer/Acetonitrile to 30/70
8-10 min Buffer/Acetonitrile to 76/24
10-20 min Buffer/Acetonitrile 76/24 (v/v);
0.1 % H_3PO_4

Detector:

DAD
215 nm

Injector:

Auto
20 μ l; 2.228 mg/ml in
Buffer solution





Area Percent Report - Sorted by Signal

Pk #	Retention Time	Area	Area %
1	3.75	1658	0.05
2	4.46	3054331	99.93
3	5.25	577	0.02
Totals		3056566	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 99.93 %
Number of results n=3
Standard deviation < 0.01 %

IIb. Water Content

Method: Karl Fischer titration

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

IIc. Residual Solvents

Method: ¹H-NMR

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



III. Final Result

Chromatographic purity (HPLC)	99.93 %
Water content	No significant amounts of water were detected (< 0.05 %).
Residual solvents	No significant amounts of residual solvents were detected (< 0.05 %).
Assay (100 % method)¹	99.93 %

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, 2016-12-09

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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