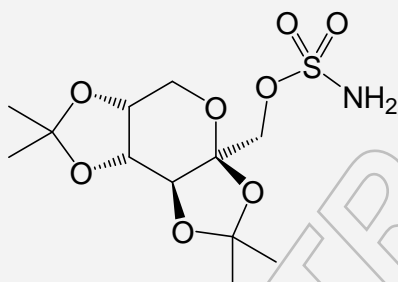


Certificate of Analysis

Reference Substance

Topiramate

Catalogue Number:	LGCFOR1348.00	Long-term Storage:	2 to 8 °C, dark
Lot Number:	14580	Appearance:	white solid
Molecular Formula:	C ₁₂ H ₂₁ NO ₈ S	Melting Point:	126 °C
Molecular Weight:	339.36	Assay 'as is':	99.2 %
CAS Number:	[97240-79-4]		



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.

Release Date: 2012-05-29

LGC GmbH



Dr. Sabine Schröder
Product Release

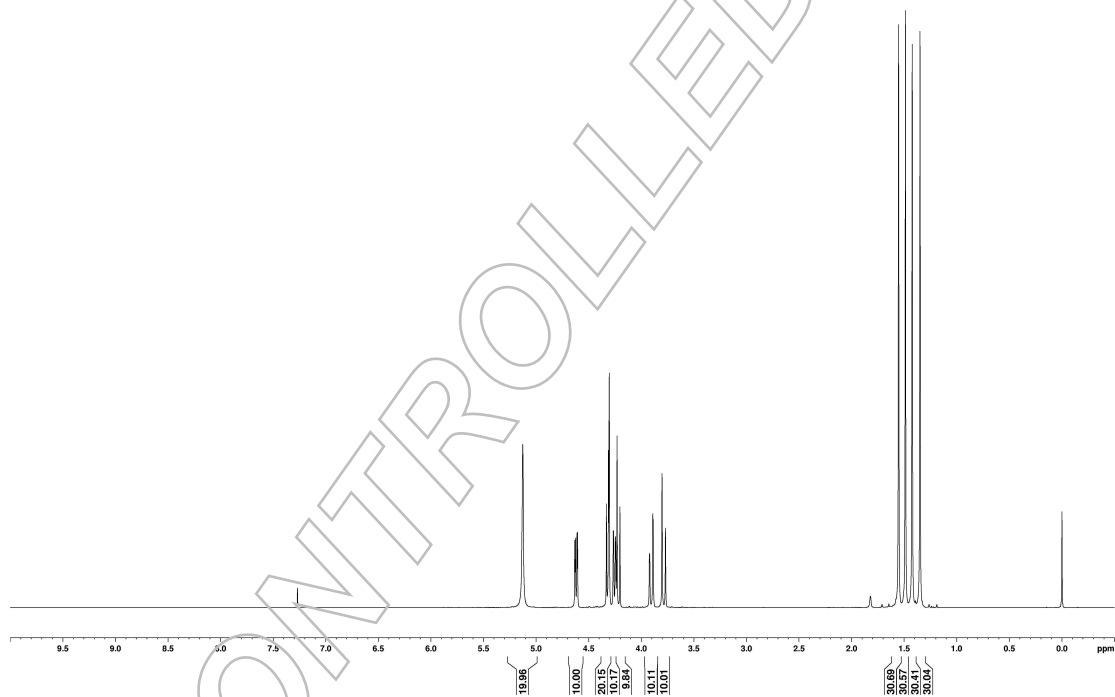
I. Identity

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

Ia. ¹H-NMR Spectrum

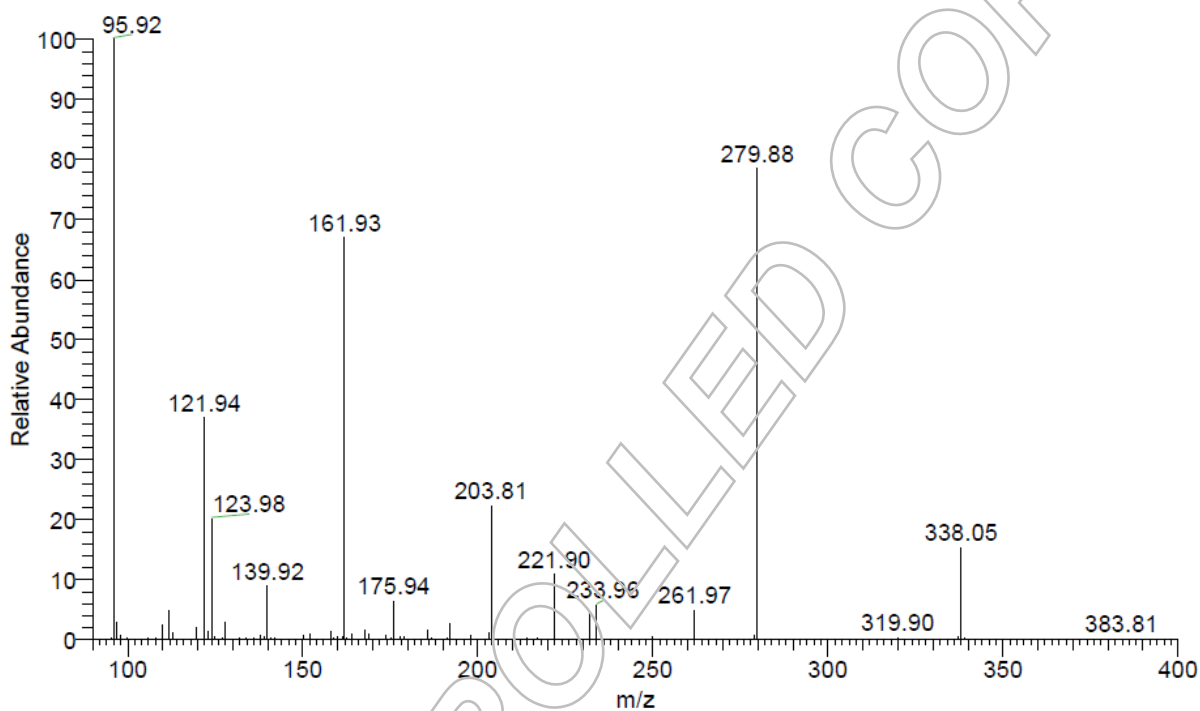
Conditions: 400 MHz, CDCl₃

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



Ib. Mass Spectrum

Method: 4.5 kV ESI; vaporization temperature: 200 °C, direct inlet

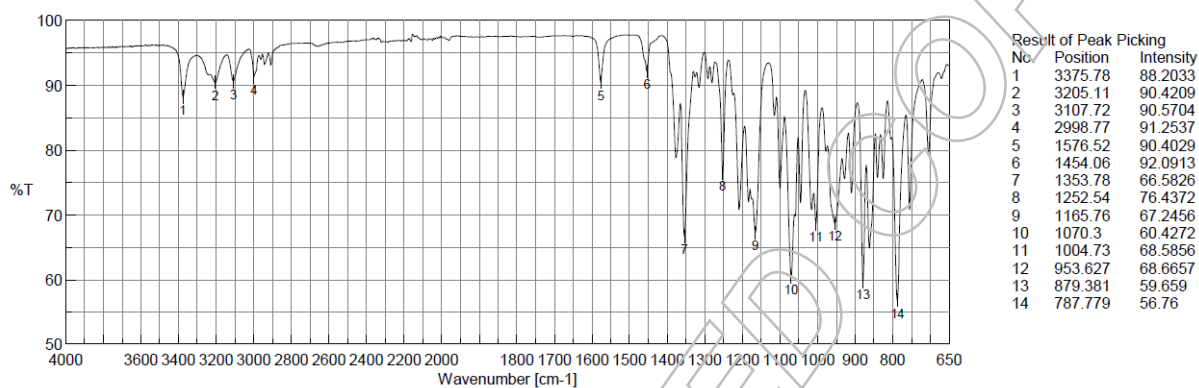


m/z	fragments
338	[M - H]
280	[M - H - C ₃ H ₆ O]
262	[280 - H ₂ O]
96	[H ₂ NSO ₃]

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



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

II. Purity

The purity of the reference substance (neat material) was analysed by gas chromatography (GC).

GC Conditions:

Column:

HP-5MS

30 m x 0.25 mm x 0.25 µm

Injector and Flow:

Split 20:1, 220 °C

Helium 1.50 ml/min

Oven Program:

Initial Temp.: 70 °C for 3 min

Heating Rate: 30 °C/min

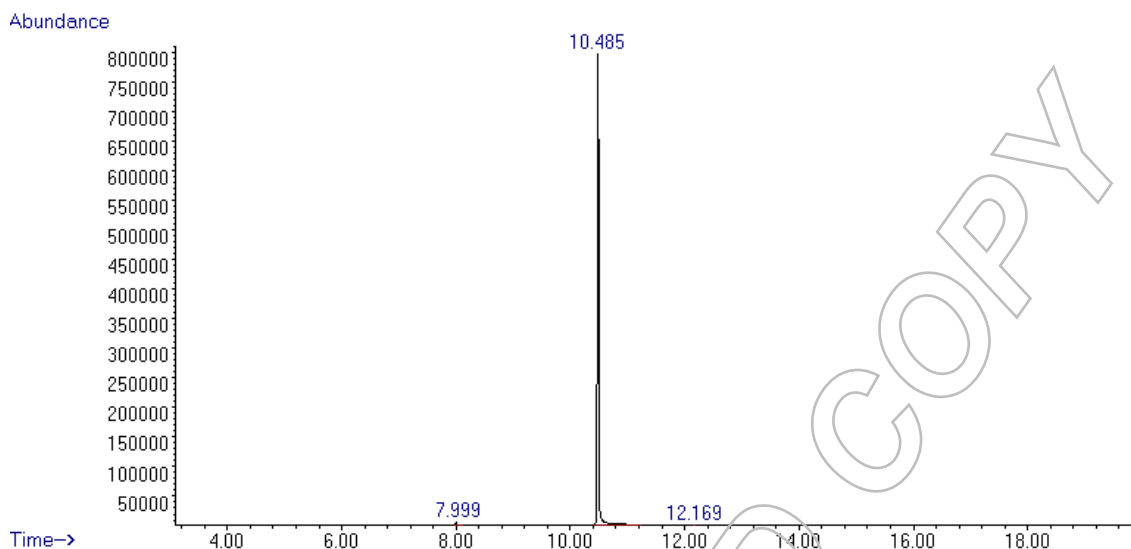
Final Temp.: 250 °C for 11 min

Detector:

EI, 70 eV

35 to 550 amu

280 °C



Area Percent Report - Sorted by Signal

Pk #	Retention Time	Area	Area %
1	7.999	88403	0.699
2	10.485	12552587	99.264
3	12.169	4688	0.037
Totals		12645678	100.00

For the calculation the air 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 99.22 %
Number of results n=3
Standard deviation 0.07 %

III. Water Content

Method: Karl Fischer titration

Results:

Average	0.06 %
Number of results	n=3
Standard deviation	0.01 %

IV. Residual Solvents

Method: ¹H-NMR

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

V. Final Result

Total impurities (GC)	0.78 %
Water content	0.06 %
Residual solvents	n. d. (not detected)
Assay (100 % method) ¹	99.16 %

The assay is assessed to be 99.2 % 'as is'

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

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

$$\text{Assay (\%)} = (100 \% - \text{KF} - \text{RES}) \times \frac{\text{Purity GC (\%)}}{100 \%}$$

Water (KF) and Residual solvents (RES) are considered as absolute contributions, GC purity is considered as relative contribution.

LGCFOR1348.00 Lot Number 14580

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