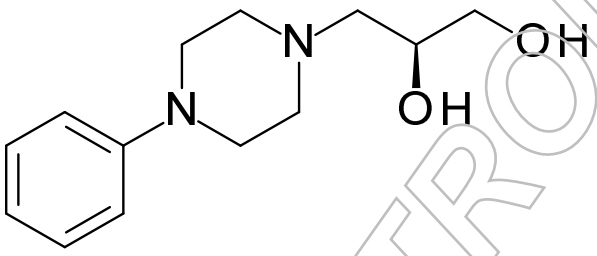
Certificate of Analysis

Reference Standard

Levodropropizine



Molecular Formula:	$C_{13}H_{20}N_2O_2$
Molecular Weight:	236.31
CAS Number:	99291-25-5

Catalogue Number:	LGCFOR1246.00
Lot Number:	68539
Long-term Storage:	2 to 8 °C, dark
Appearance:	white solid
Melting Point (DSC):	104 °C
Assay 'as is':	100 %

Date of shipment: **2017-September-05**

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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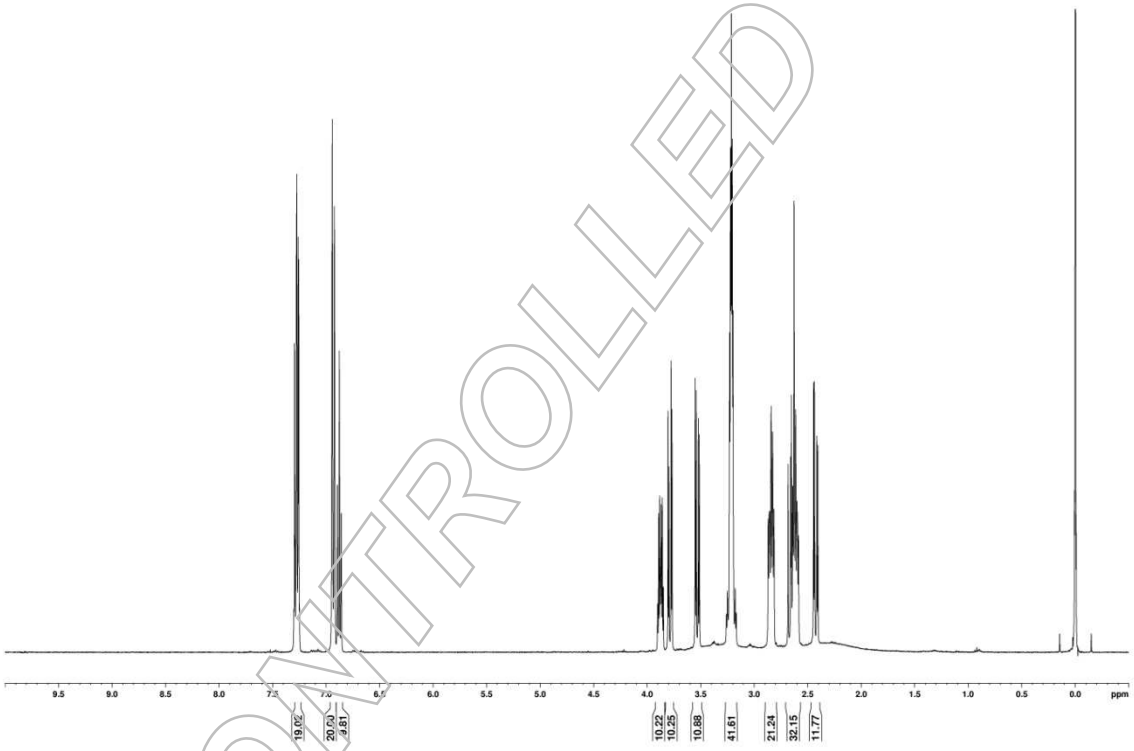
I. Identity

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

Ia. ^{1}H-NMR Spectrum

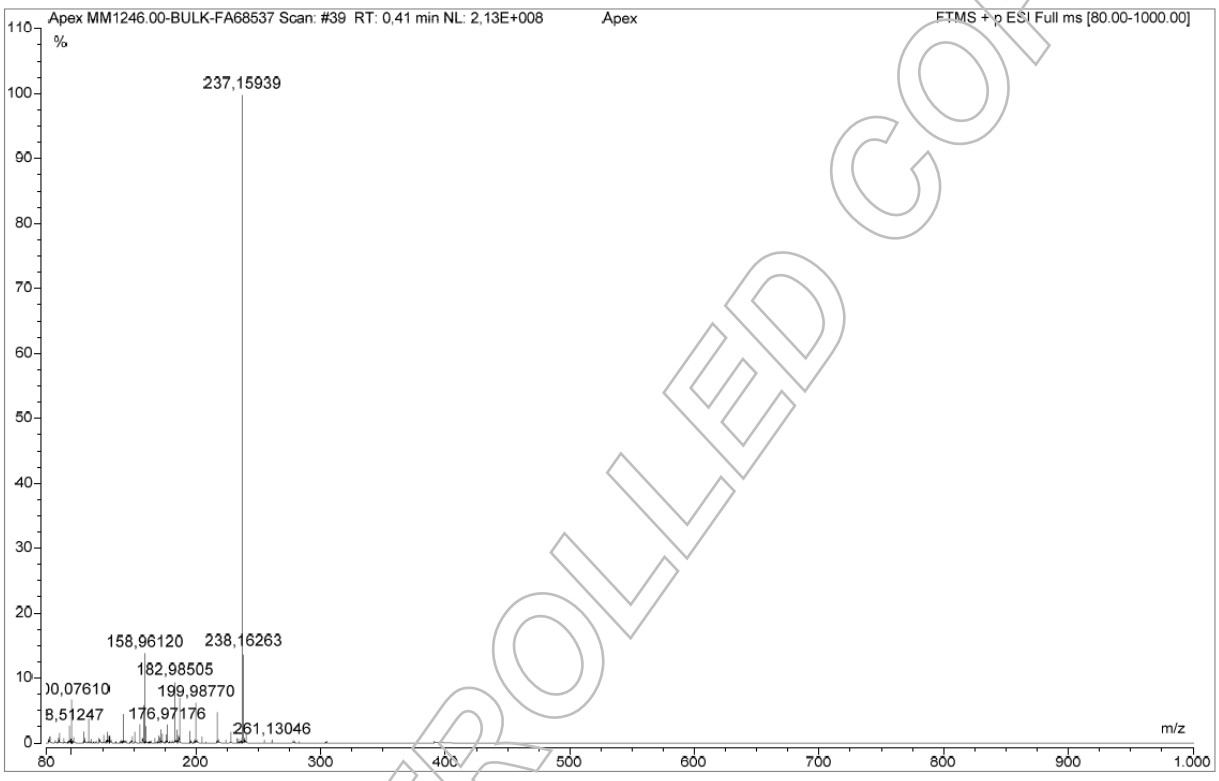
Conditions: 400 MHz, $CDCl_3$



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

Ib. Mass Spectrum

Method: 3.5 kV ESI+; capillary temperature: 269 °C

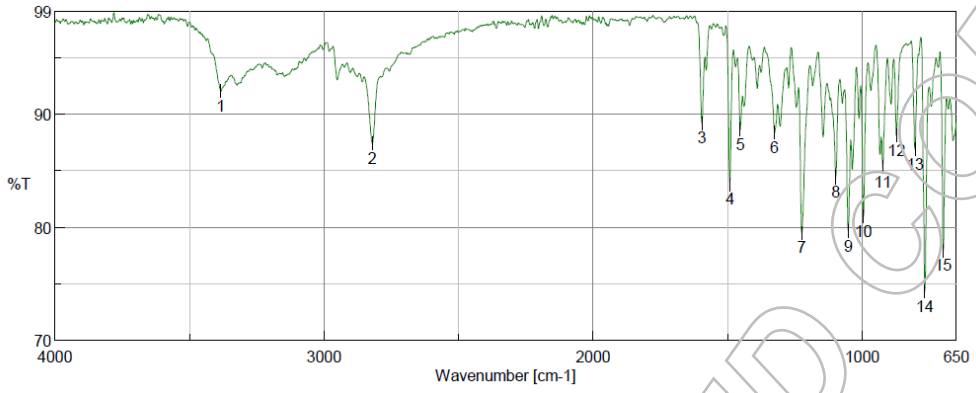


Theoretical value: 237.15975

The signal of the MS spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

Ic. IR Spectrum

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



Results of Peak Find

No.	Position	Intensity
1	3382.53	91.9817
2	2820.38	87.3517
3	1595.81	89.1194
4	1491.67	83.7621
5	1453.1	88.6012
6	1325.82	88.338
7	1224.58	79.4835
8	1097.3	84.3728
9	1051.98	79.6459
10	995.089	80.9191
11	922.771	85.2968
12	872.631	88.057
13	804.171	86.8477
14	766.566	74.3126
15	699.069	77.9136

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

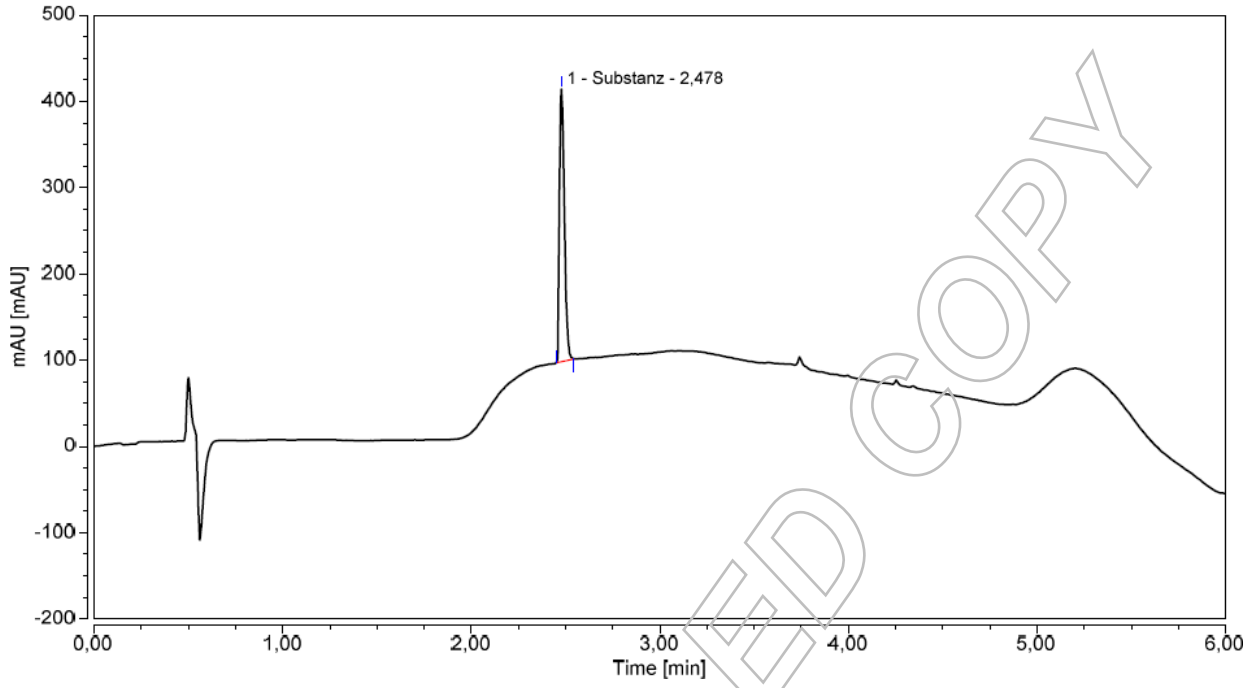
II. Purity

IIa. High Performance Liquid Chromatography (HPLC)

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

HPLC Conditions:

Column:	Conditions:	Detector:	Injector:
Kinetex Phenyl-Hexyl 1.7 µm, 100 x 2.1 mm	0.5 ml/min, 40 °C 0-1 min Water/Acetonitrile 98/2 1-4 min Water/Acetonitrile to 2/98 4-5 min Water/Acetonitrile to 98/2 5-6 min Water/Acetonitrile 98/2 (v/v); 0.1 % HCOOH	DAD 210 nm	Auto 1 µl; 0.05 mg/ml in Water/Acetonitrile 50/50 (v/v)



Area Percent Report - Sorted by Signal

Pk #	Retention Time	Area	Area %
1	2.478	9.627	100.00
Totals		9.627	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	100 %
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: ^{1}H-NMR

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

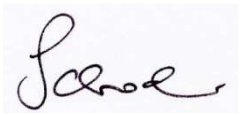
III. Final Result

Chromatographic purity (HPLC)	100.00 %
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]	100.00 %

The assay is assessed to be 100 % 'as is'

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

Release Date:
Luckenwalde, 2015-03-04



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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