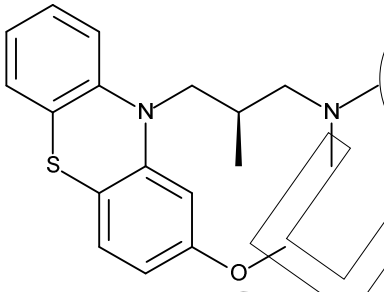
Certificate of Analysis

Reference Standard

Levomepromazine Hydrochloride



Molecular Formula:	$C_{19}H_{24}N_2OS \cdot HCl$
Molecular Weight:	364.93
CAS Number:	1236-99-3

Catalogue Number:	LGCFOR0266.00
Lot Number:	1239707
Long-term Storage:	2 to 8 °C, dark
Appearance:	white solid hygroscopic
Melting Point (DSC):	144 °C
Assay 'as is':	99.4 %

Date of shipment: **2022-May-03**

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.

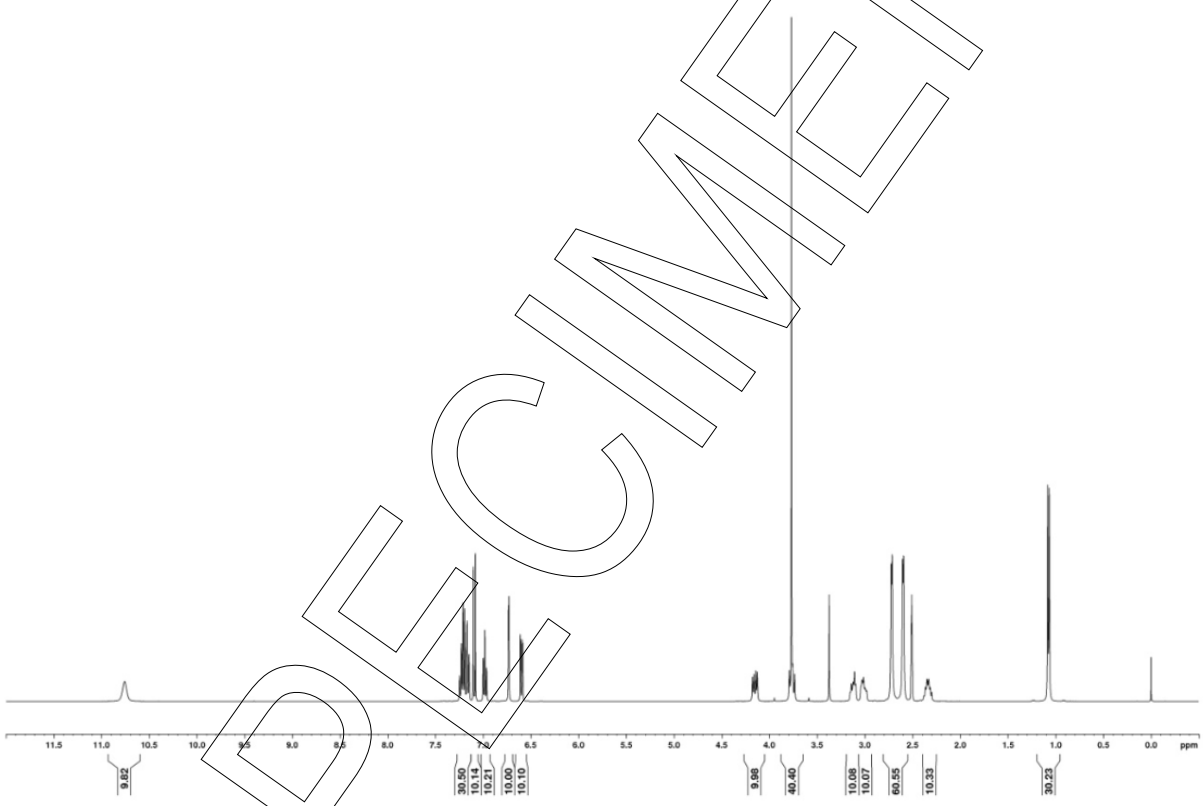
LGC GmbH, Louis-Pasteur-Str. 30, D-14943 Luckenwalde, Germany

I. Identity

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

Ia. ^{1}H-NMR Spectrum

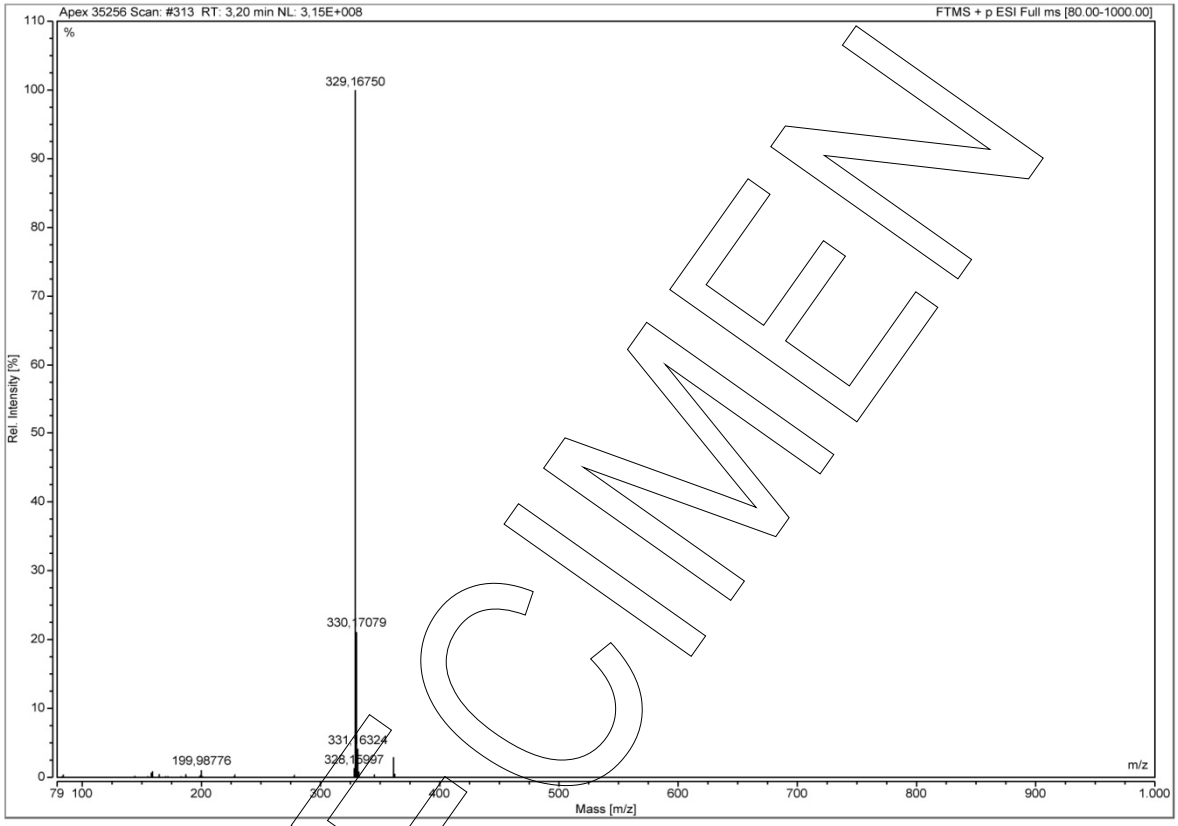
Conditions: 400 MHz, DMSO-d_6



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

Ib. Mass Spectrum

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

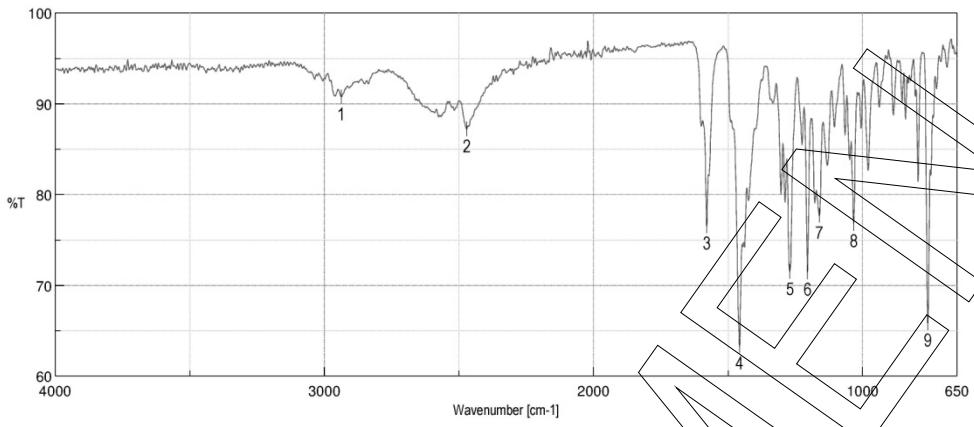


Theoretical value: 329.16821

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	2937.06	90.7394
2	2471.33	87.2131
3	1579.41	76.5269
4	1457.92	63.3109
5	1270.86	71.521
6	1205.29	71.4335
7	1160.94	77.6882
8	1033.66	76.804
9	757.888	65.8218

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

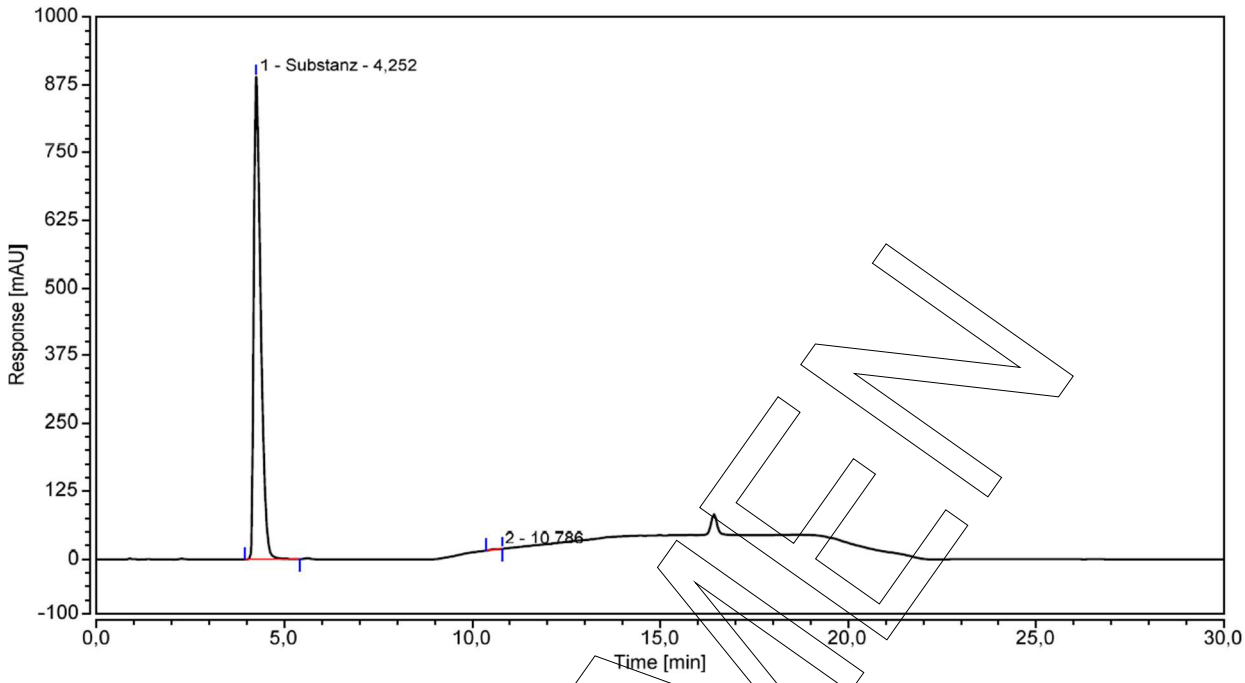
II. Purity

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:**
LiChrospher 60 RP-select B 5 µm, 125 x 4 mm	1.0 ml/min, 40 °C 0-7 min Water/Acetonitrile 60/40 7-12 min Water/Acetonitrile to 20/80 12-17 min Water/Acetonitrile 20/80 17-20 min Water/Acetonitrile to 60/40 20-30 min Water/Acetonitrile 60/40 (v/v); 0.1 % H_3PO_4	DAD 210 nm	Auto 5 µl; 0.103 mg/ml in Water/Acetonitrile 50/50 (v/v)



Area Percent Report - Sorted by Signal

Pk #	Retention Time	Area	Area %
1	4.252	188.615	99.92
2	10.786	0.160	0.08
Totals		188.775	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	99.92 %
Number of results	n=6
Standard deviation	0.01 %

IIb. Water Content

Method: Karl Fischer titration

Results:

Average	0.56 %
Number of results	n=3
Standard deviation	< 0.01 %

IIc. Residual Solvents

Method: ^{1}H-NMR

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

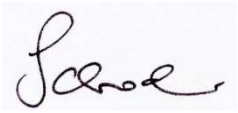
III. Final Result

Chromatographic purity (HPLC)	99.92 %
Water content	0.56 %
Residual solvents	No significant amounts of residual solvents were detected (< 0.05 %).
Assay (100 % method)[1]	99.36 %

The assay is assessed to be 99.4 % 'as is'

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

Release Date:
Luckenwalde, 2022-03-24



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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