

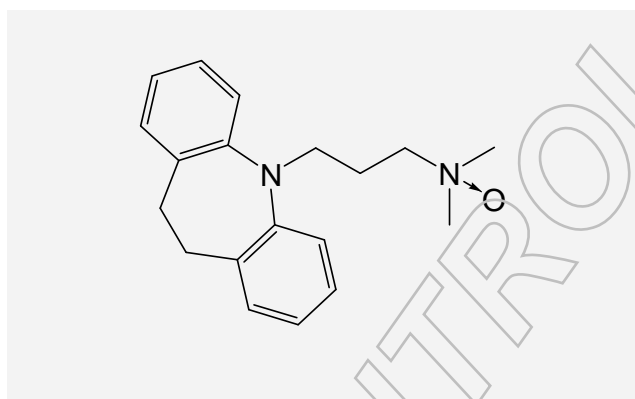
Certificate of Analysis

Reference Substance

Imipramine N-Oxide

Catalogue Number: LGCFOR0077.12
Lot Number: 2387
Molecular Formula: C₁₉H₂₄N₂O
Molecular Weight: 296.41
CAS Number: [6829-98-7]

Long-term Storage: 2 to 8 °C, dark
Appearance: off-white solid
Melting Point: 87 °C
very hygroscopic
Assay 'as is': 93.1 %



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: 2010-05-28

LGC GmbH



Dr. Sabine Schröder

Product Release

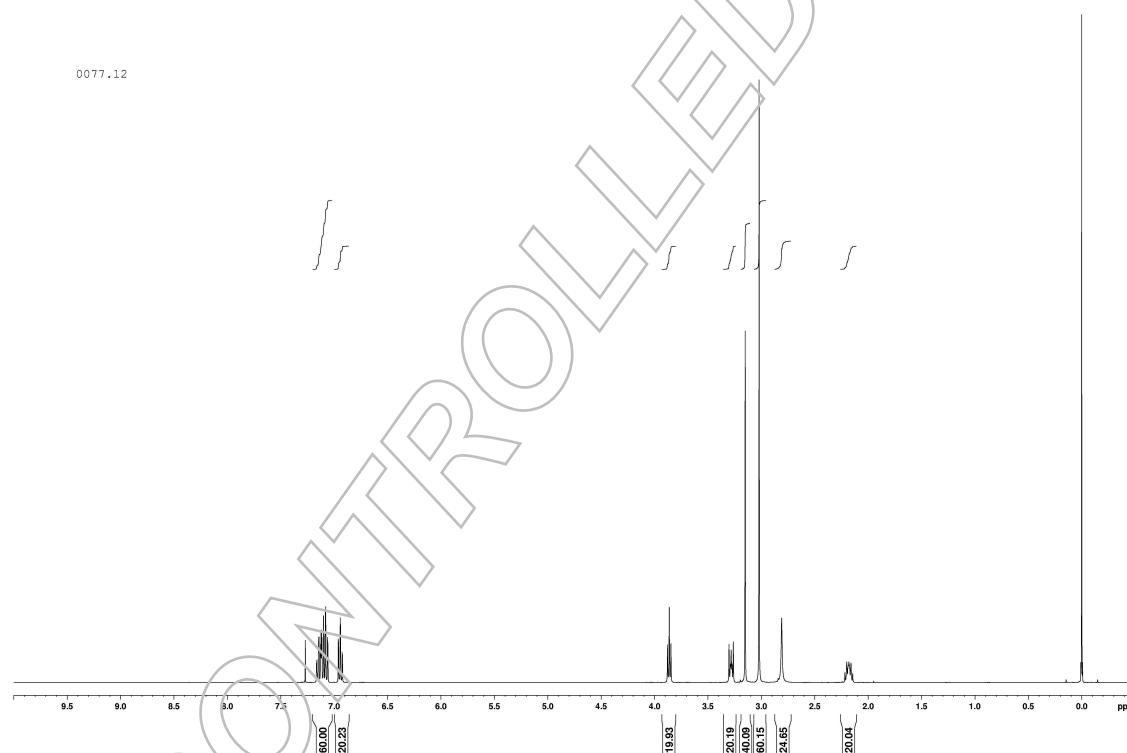
I. Identity

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

Ia. ¹H-NMR Spectrum

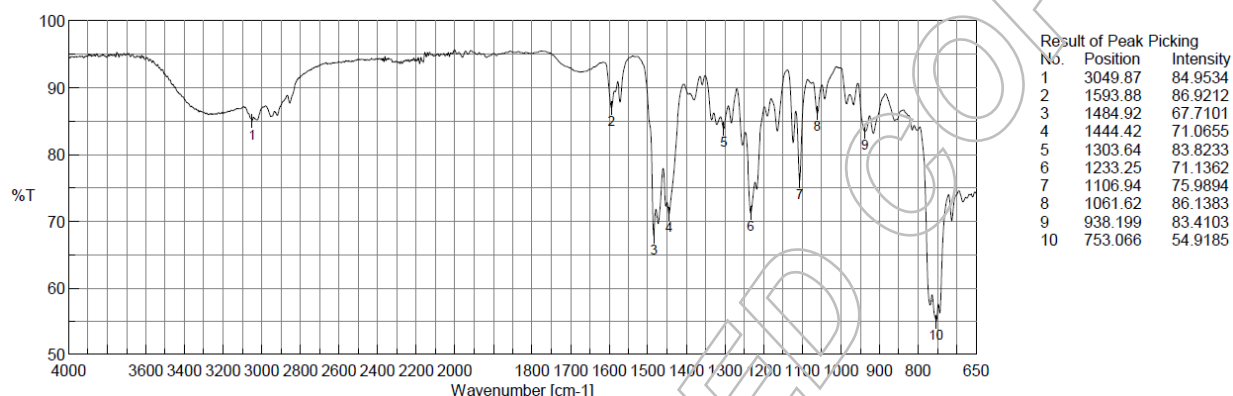
Conditions: 400 MHz, CDCl₃

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



Ib. 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 was analysed by high performance liquid chromatography (HPLC).

HPLC Conditions:

Column:

RP 60 Select B
5 µm, 125 x 4 mm

Conditions:

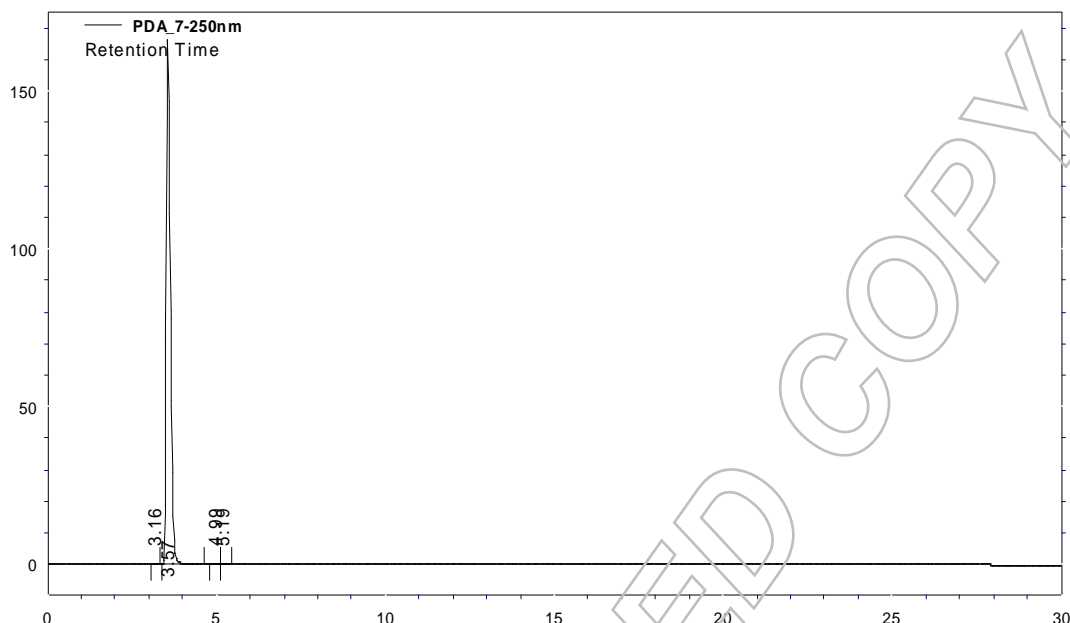
1.0 ml/min, 40 °C
Water/Acetonitrile 55/45 (v/v);
0.1 % H₃PO₄

Detector:

DAD
250 nm

Injector:

Auto
4 µl; 0.0502 mg/ml in
Water/Acetonitrile 50/50 (v/v)



Area Percent Report - Sorted by Signal

Pk #	Retention Time	Area	Area %
1	3.16	1121	0.08
2	3.57	1365362	99.60
3	4.99	3730	0.27
4	5.19	586	0.04
Totals		1370799	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 99.61 %
Number of results n=6
Standard deviation 0.02 %

III. Loss on Drying

Method: TGA

Results:

Average	6.57 %
Number of results	n=3
Standard deviation	0.21 %

IV. Final Result

Total impurities (HPLC)	0.39 %
Loss on drying	6.57 %
Assay (100 % method) ¹	93.07 %

The assay is assessed to be 93.1 % 'as is'

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

The calculation of the 100 % method follows the formula:

$$\text{Assay (\%)} = (100 \% - \text{LOD}) \times \frac{\text{Purity HPLC (\%)}}{100 \%}$$

The sum of Water and Residual solvents (LOD) is considered as absolute contributions, HPLC purity is considered as relative contribution.

LGCFOR0077.12 Lot Number 2387

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