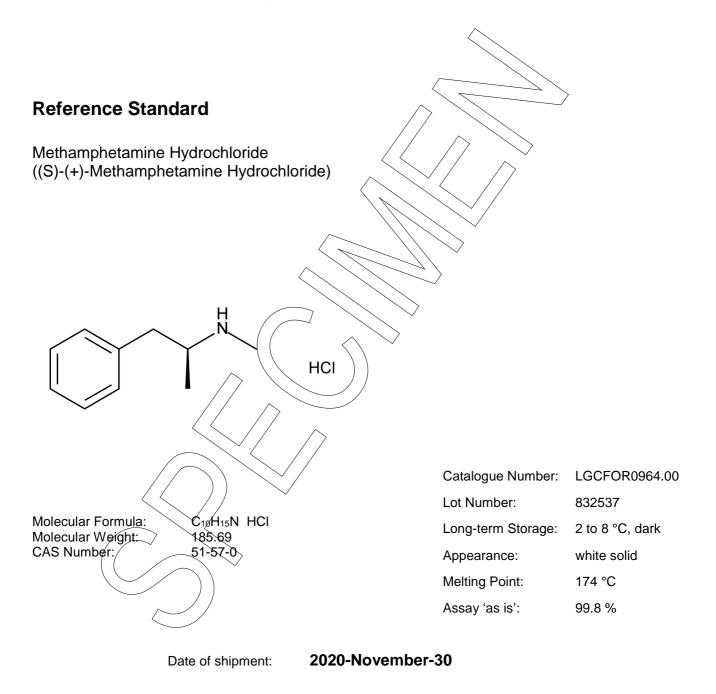


# **Certificate of Analysis**



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

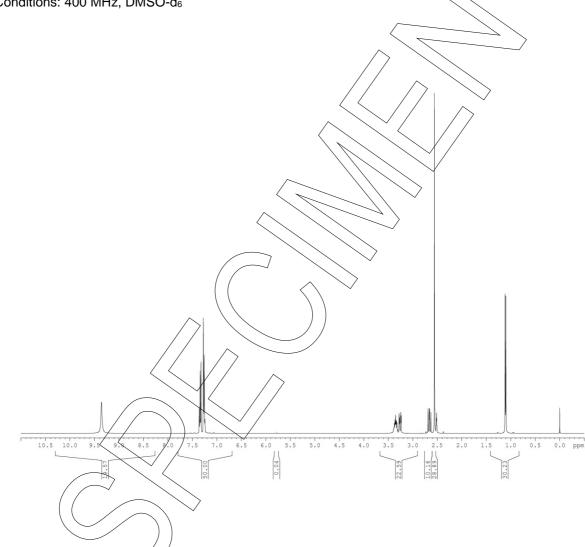
LGC Quality



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

#### <sup>1</sup>H-NMR Spectrum la.

Conditions: 400 MHz, DMSO-d<sub>6</sub>

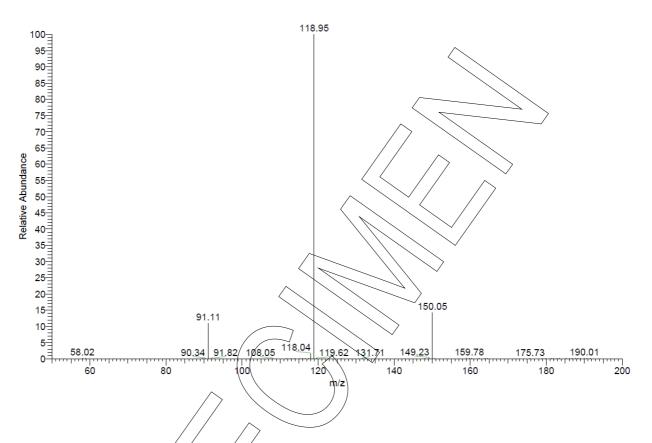


The structure is confirmed by the signals of the spectrum and their interpretation.

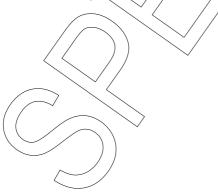




Method: 4.5 kV ESI+; vaporization temperature: 200 °C



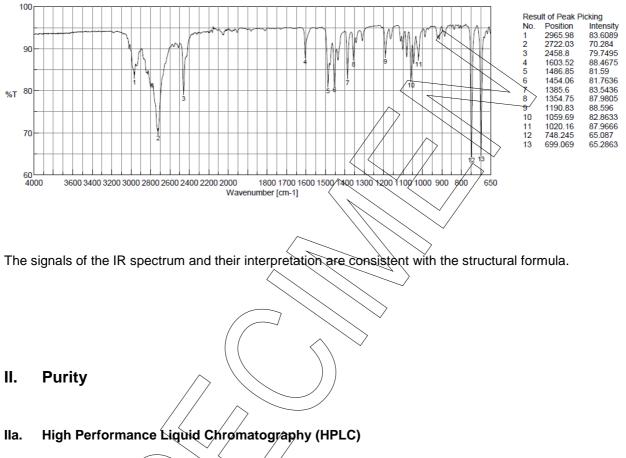
The signals of the mass spectrum and their interpretation are consistent with the structural formula.







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



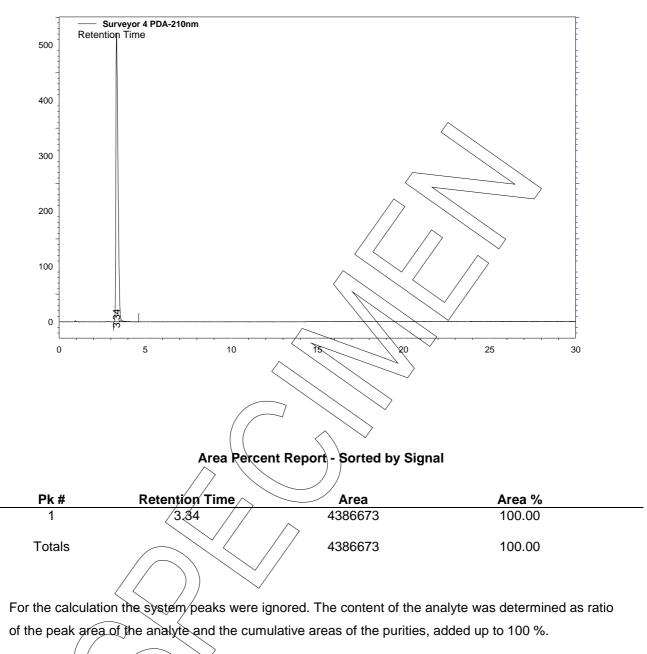
The purity of the reference substance was analysed by high performance liquid chromatography (HPLC).

### **HPLC Conditions:**

Column: Conditions:	Detector:	Injector:
LiChrospher	DAD	Auto
60 RP-select B		
5 μm, 125 x 4 mm Water/Acetonitrile 85/15 (v/v);	210 nm	8 µl; 0.0706 mg/ml in
0.1 % H <sub>3</sub> PO <sub>4</sub>		Water/Acetonitrile 85/15 (v/v)







) %
%





Method: Karl Fischer titration

#### **Results:**

Average	0.11 %
Number of results	n=3
Standard deviation	0.01 %

### IIc. Residual Solvents

Method: 1H-NMR

Result: 0.09 % Dichloromethane

## III. Final Result

Chromatographic purity (HPLC) Water content Residual solvents Assay (100 % method)<sup>1</sup>

The assay is assessed to be 99.8 % 'as is'

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

100.00 %

0.11%

0.09 %

99.80 %

Release Date:

Luckenwalde, 2018-06-19

Dr. Sabine Schröder Product Release

<sup>1</sup> The calculation of the 100 % method follows the formula:

Assay (%) = (100 % - volatile contents) \*

Purity (%) 100 %

Volatile contents are considered as absolute contributions, purity is considered as relative contribution.



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