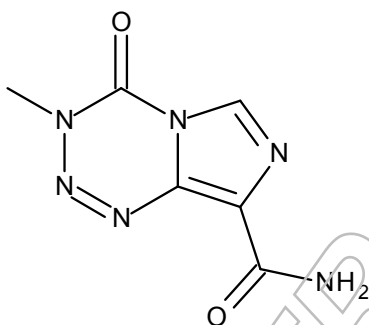




# Certificate of Analysis

## Reference Standard

Temozolomide



Molecular Formula:  $C_6H_6N_6O_2$   
Molecular Weight: 194.15  
CAS Number: 85622-93-1

Catalogue Number: MM1480.00  
Lot Number: 63615  
Long-term Storage: 2 to 8 °C, dark  
Appearance: white solid  
Assay 'as is': 99.8 %

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

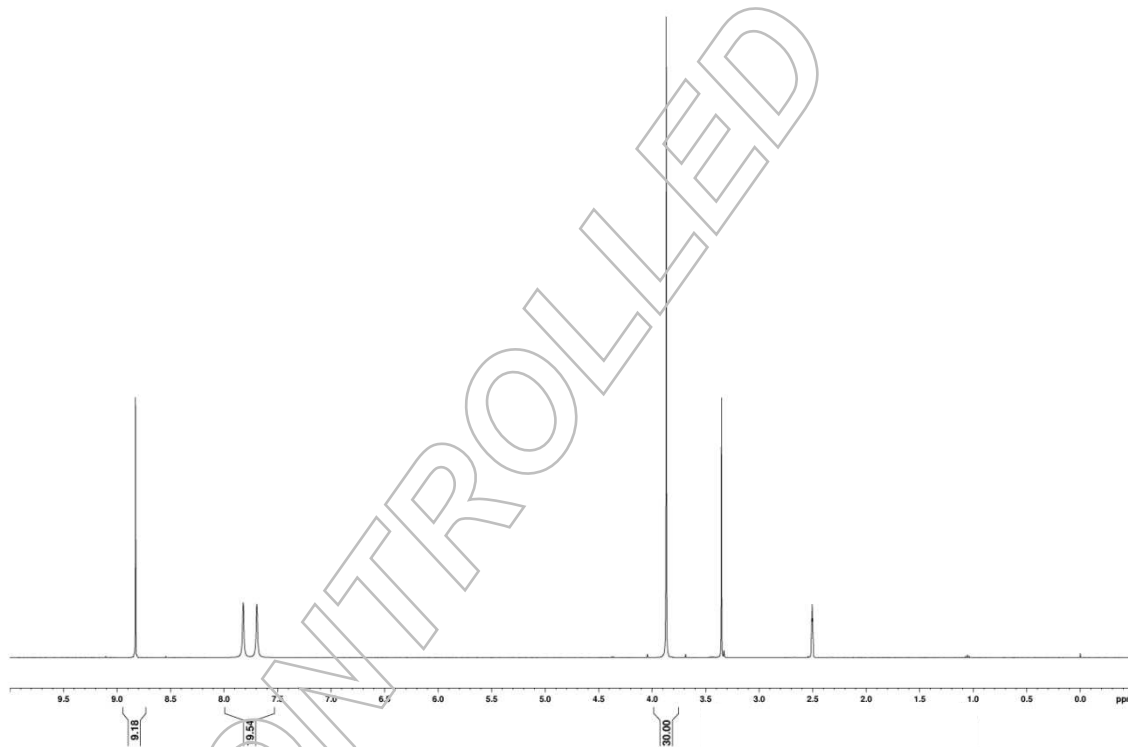


## I. Identity

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

### 1a. $^1\text{H-NMR}$ Spectrum

Conditions: 400 MHz,  $\text{DMSO-d}_6$

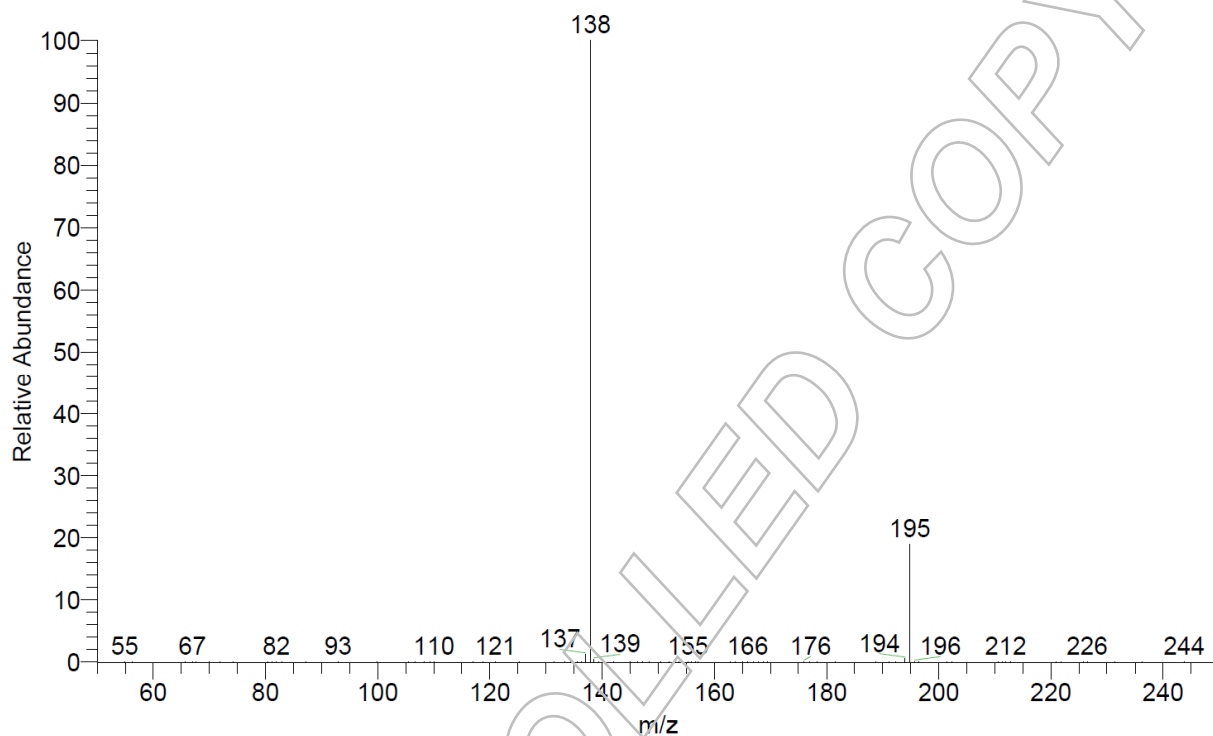


The structure is confirmed by the signals of the spectrum and their interpretation.



### Ib. Mass Spectrum

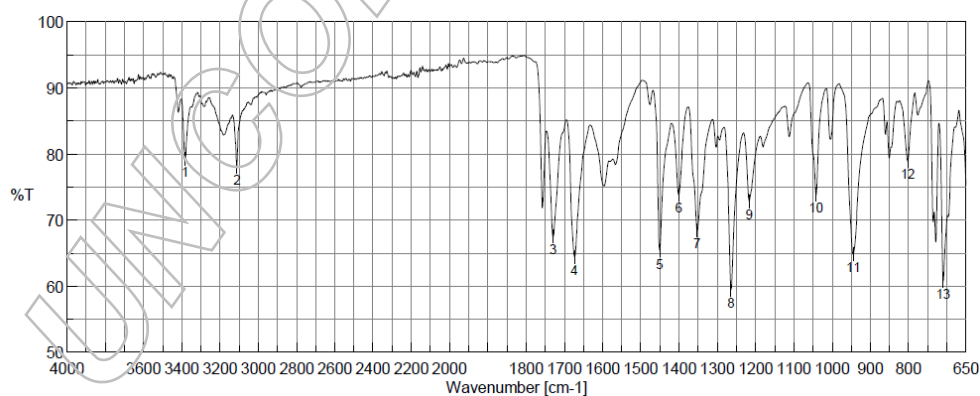
Method: 4.5 kV ESI+; vaporization temperature: 200 °C



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



Result of Peak Picking		
No.	Position	Intensity
1	3382.53	79.1618
2	3112.55	78.0313
3	1729.83	67.4661
4	1673.91	64.4266
5	1450.21	65.3386
6	1401.03	73.7965
7	1352.82	68.4119
8	1264.11	59.4778
9	1216.86	72.8457
10	1042.34	73.7594
11	944.949	64.8139
12	802.242	78.8907
13	709.676	60.7068

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:**

ZORBAX Phenyl  
5 µm, 250 x 4.6 mm

**Conditions:**

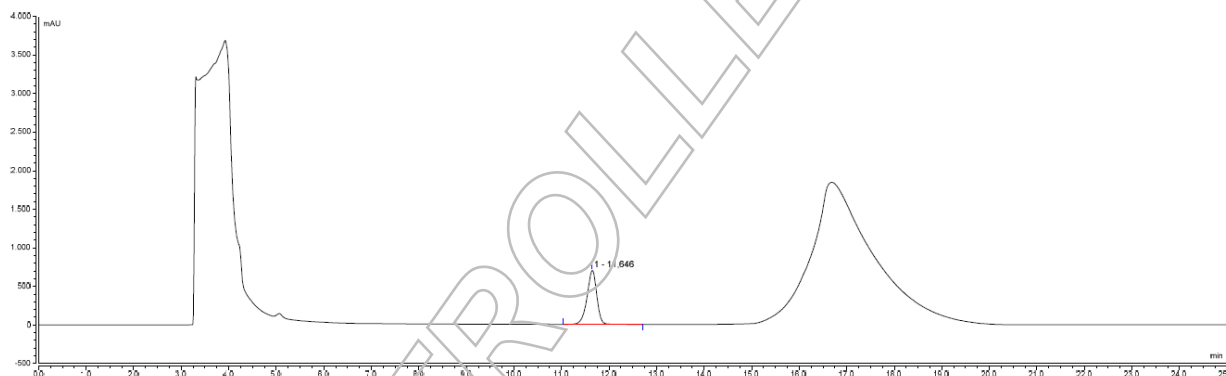
1.0 ml/min, 40 °C  
0-10 min Water/Acetonitrile 94/6  
10-13 min Water/Acetonitrile to 60/40  
13-15 min Water/Acetonitrile to 94/6  
15-25 min Water/Acetonitrile 94/6 (v/v);  
0.1 % H<sub>3</sub>PO<sub>4</sub>

**Detector:**

DAD  
210 nm

**Injector:**

Auto  
3 µl; 0.16072 mg/ml in  
Dimethyl sulfoxide



#### Area Percent Report - Sorted by Signal

Pk #	Retention Time	Area	Area %
1	11.646	166.2936	100.00
Totals		166.2936	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=6  
**Standard deviation** < 0.01 %



## IIb. Water Content

Method: Karl Fischer titration

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

## IIc. Residual Solvents

Method: <sup>1</sup>H-NMR

Result: 0.16 % Ethanol

## III. Assay by Elementary Analysis (Carbon Titration)

Method: percentage carbon found in relation to percentage carbon as calculated for molecular formula

### Results:

Arithmetic mean (n=3) 99.97 % (mass fraction)

## IV. Final Result

Chromatographic purity (HPLC)	100 %
Water content	No significant amounts of water were detected (< 0.05 %).
Residual solvents	0.16 %
Assay (100 % method) <sup>1</sup>	99.84 %

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.

Release Date:

Luckenwalde, 2015-08-24

Dr. Sabine Schröder  
Product Release

<sup>1</sup> 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.