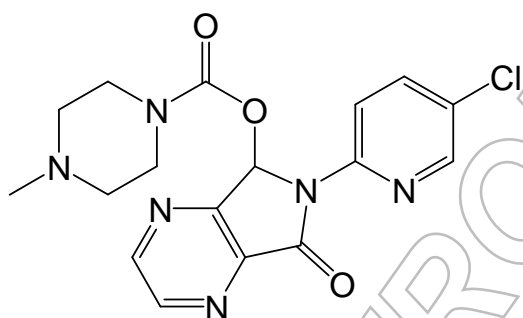




Certificate of Analysis

Reference Standard

Zopiclone



Molecular Formula: $C_{17}H_{17}ClN_6O_3$
Molecular Weight: 388.81
CAS Number: [43200-80-2]

Catalogue Number: MM0149.00
Lot Number: 19118
Long-term Storage: 2 to 8 °C, dark
Appearance: light pink solid
Melting Point: 176 °C
Assay 'as is': 99.3 %

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.



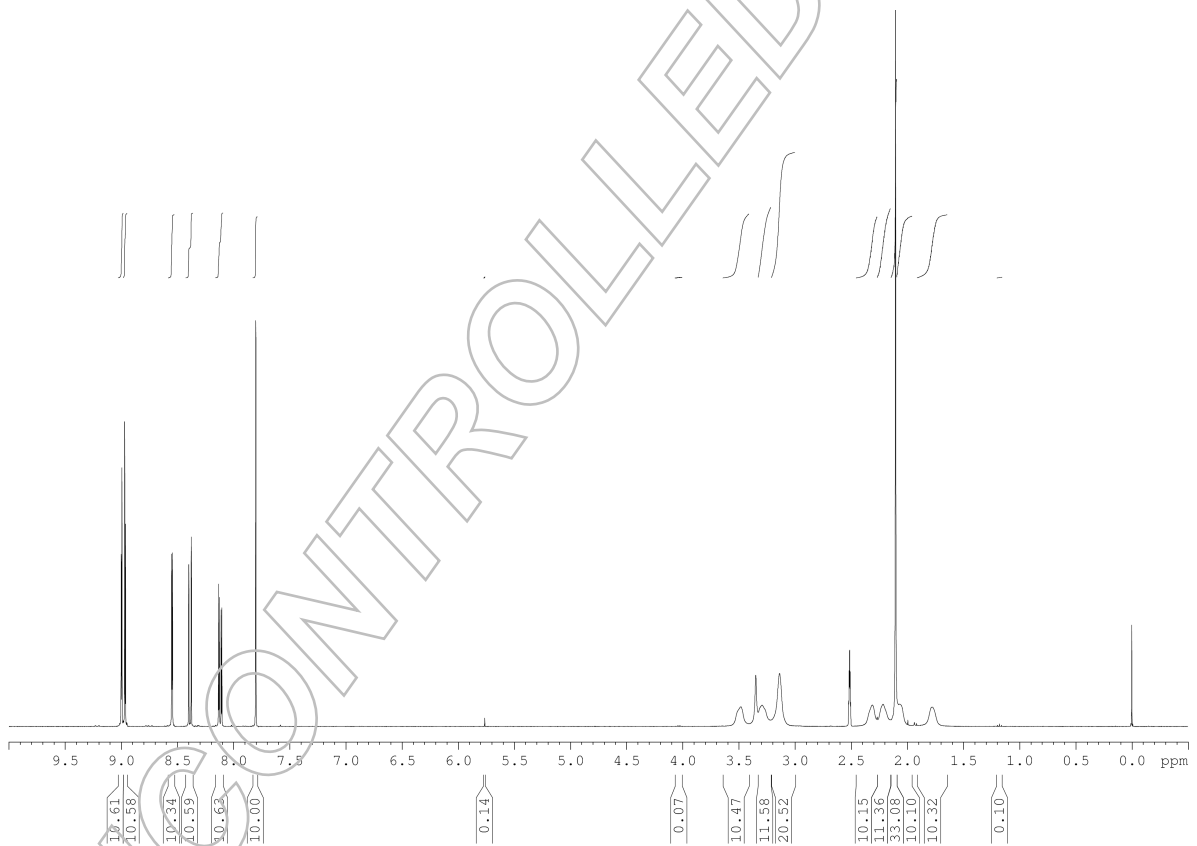
I. Identity

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

Ia. ¹H-NMR Spectrum

Conditions: 400 MHz, DMSO-d₆

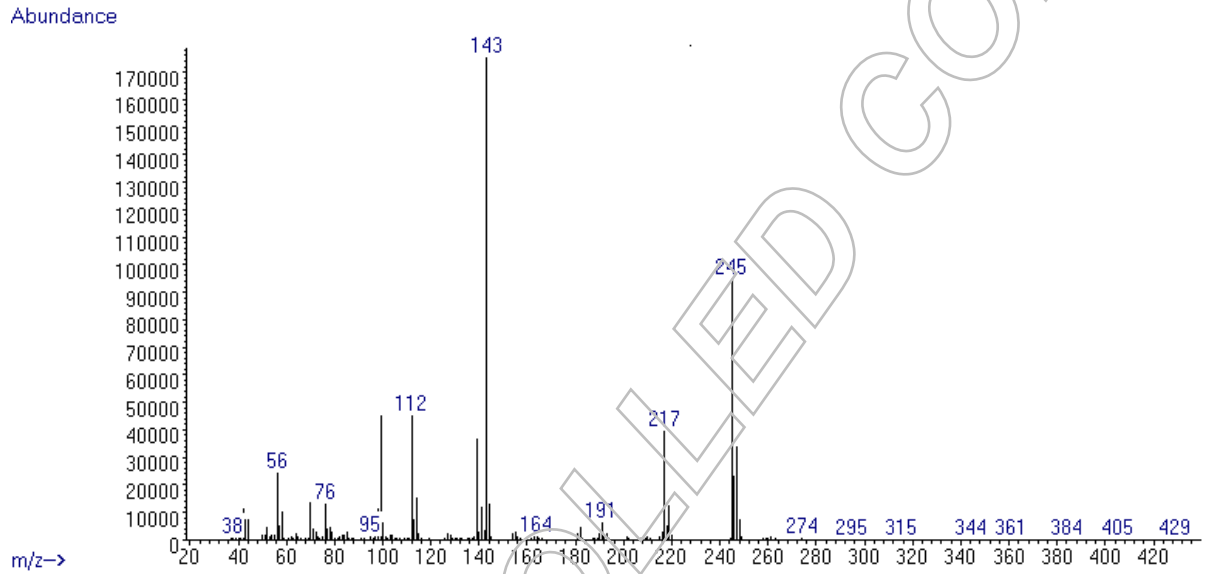
The structure is confirmed with the signals of the spectrum and their interpretation.





Ib. Mass Spectrum

Method: EI, 70eV, detector temperature: 280 °C



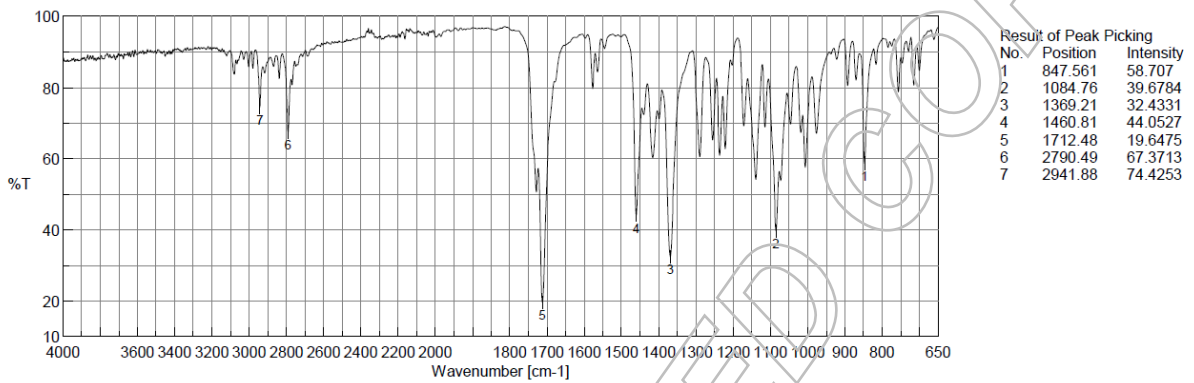
| m/z | fragments |
|-----|----------------------------------------------------------------------|
| 245 | [M - C ₆ H ₁₁ N ₂ O ₂] |
| 143 | [C ₆ H ₁₁ N ₂ O ₂] |
| 112 | [C ₅ H ₃ CIN] |

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



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:

Hypersil Gold (C18)

5 µm, 150 x 4.6 mm

Conditions:

1.0 ml/min, 30 °C

8.1 g/l Sodium laurilsulfate + 1.6 g/l
Sodium dihydrogen phosphate, pH 3.5/
Acetonitrile 62/38 (v/v)

Detector:

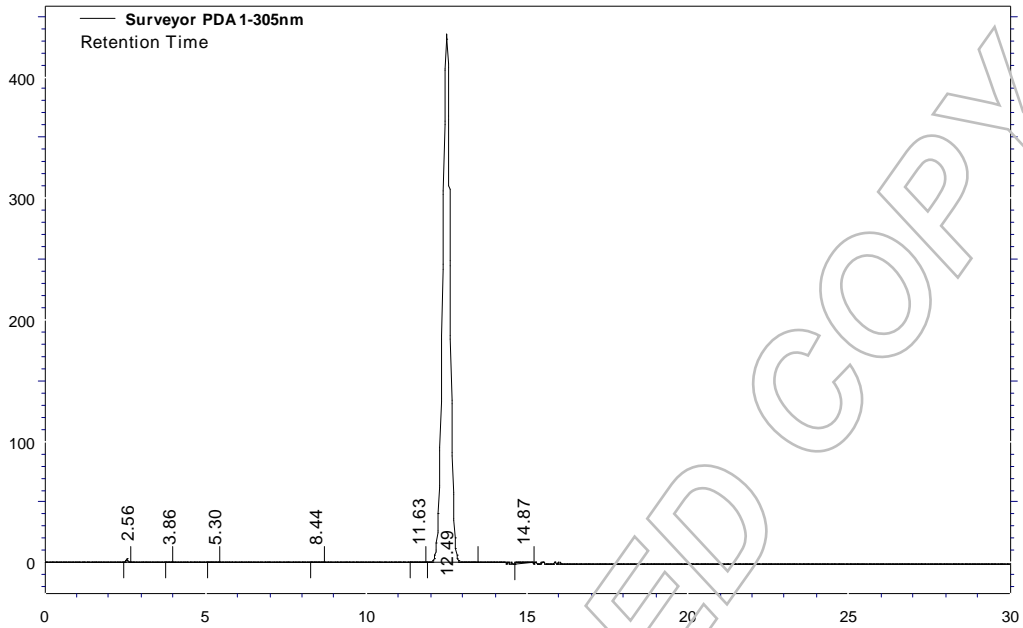
DAD

305 nm

Injector:

Auto

4 µl; 0.1796 mg/ml in
Eluent



Area Percent Report - Sorted by Signal

| Pk # | Retention Time | Area | Area % |
|--------|----------------|---------|--------|
| 1 | 2.56 | 11419 | 0.15 |
| 2 | 3.86 | 901 | 0.01 |
| 3 | 5.30 | 3623 | 0.05 |
| 4 | 8.44 | 1627 | 0.02 |
| 5 | 11.63 | 2970 | 0.04 |
| 6 | 12.49 | 7432546 | 99.70 |
| 7 | 14.87 | 1619 | 0.02 |
| Totals | | 7454705 | 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 99.70 %
Number of results n=6
Standard deviation 0.01 %



III. Water Content

Method: Karl Fischer titration

Results:

| | |
|--------------------------|--------|
| Average | 0.13 % |
| Number of results | n=2 |

IV. Residual Solvents

Method: $^1\text{H-NMR}$

Result: 0.08 % Ethyl acetate
0.15 % Dichloromethane

V. 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) | 99.60 % (mass fraction) |
|------------------------------|-------------------------|



VI. Final Result

| | |
|-----------------------------------------|---------|
| Total impurities (HPLC) | 0.30 % |
| Water content | 0.13 % |
| Residual solvents | 0.23 % |
| Assay (100 % method)¹ | 99.34 % |

The assay is assessed to be 99.3 % 'as is'

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

Release Date: 2012-10-05

LGC GmbH

Dr. Sabine Schröder
Product Release

¹ The calculation of the 100 % method follows the formula:

$$\text{Assay (\%)} = (100 \% - \text{KF} - \text{RES}) \quad * \quad \frac{\text{Purity HPLC (\%)}}{100 \%}$$

Water (KF) and Residual solvents (RES) are considered as absolute contributions, HPLC purity is considered as relative contribution.