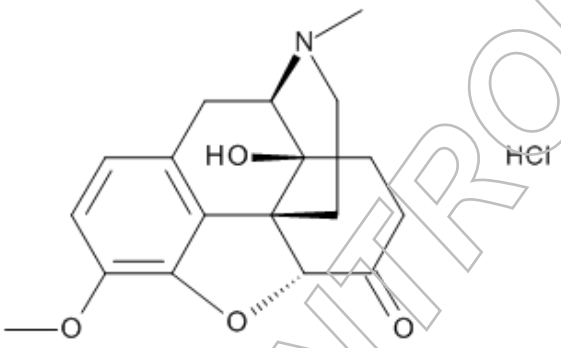
Certificate of Analysis

Reference Standard

Oxycodone Hydrochloride



Molecular Formula:	$C_{18}H_{21}NO_4$ HCl
Molecular Weight:	351.82
CAS Number:	124-90-3

Catalogue Number:	LGCFOR0672.00
Lot Number:	78477
Long-term Storage:	2 to 8 °C, dark
Appearance:	white solid
Melting Point:	270 °C
Assay 'as is':	94.4 %

Date of shipment: **2016-May-20**

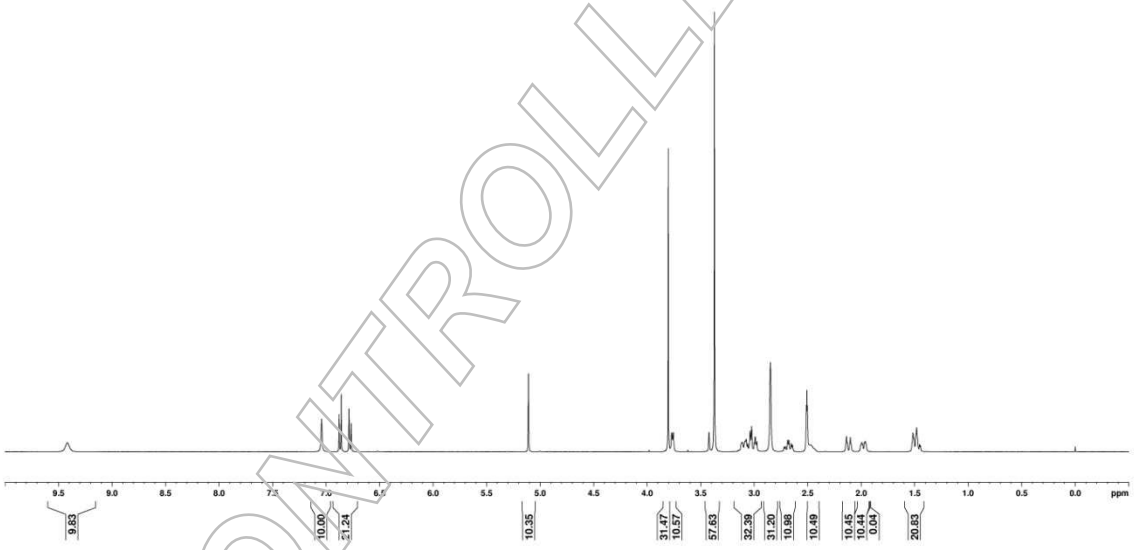
This certificate is valid for two years from the date of shipment provided the substance is stored under the recommended conditions unopened in the original container.

I. Identity

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

Ia. ^{1}H-NMR Spectrum

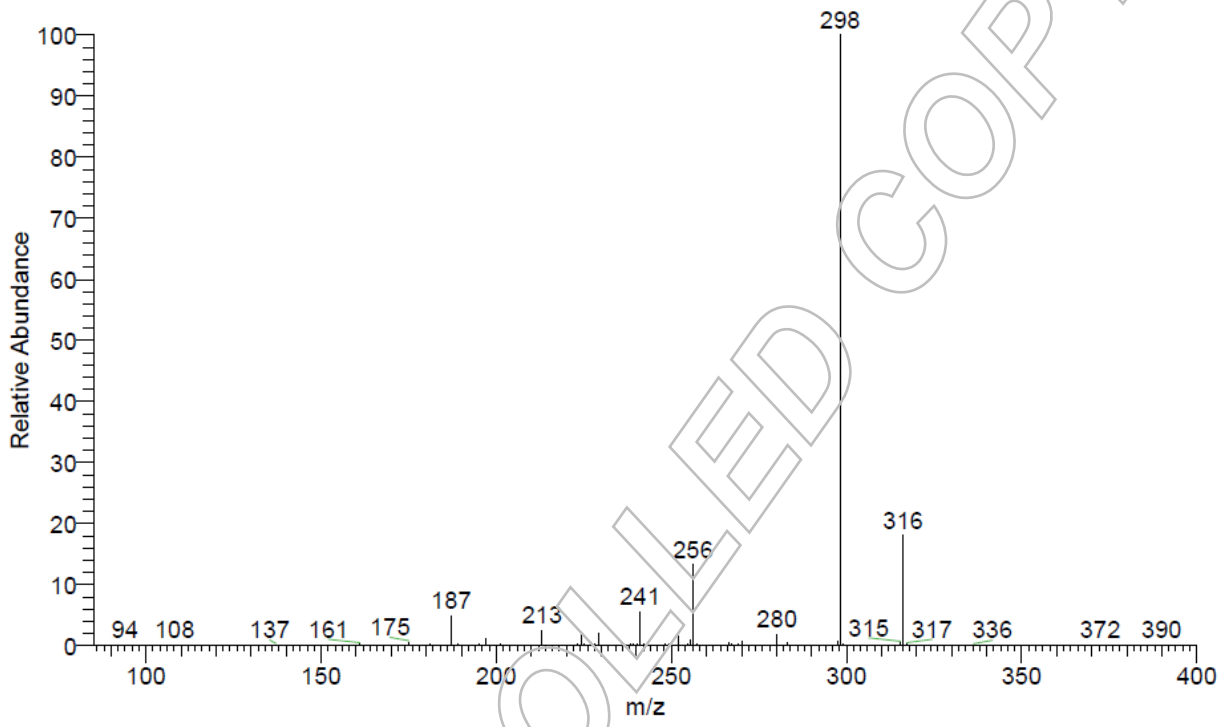
Conditions: 400 MHz, DMSO-d_6



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

Ib. Mass Spectrum

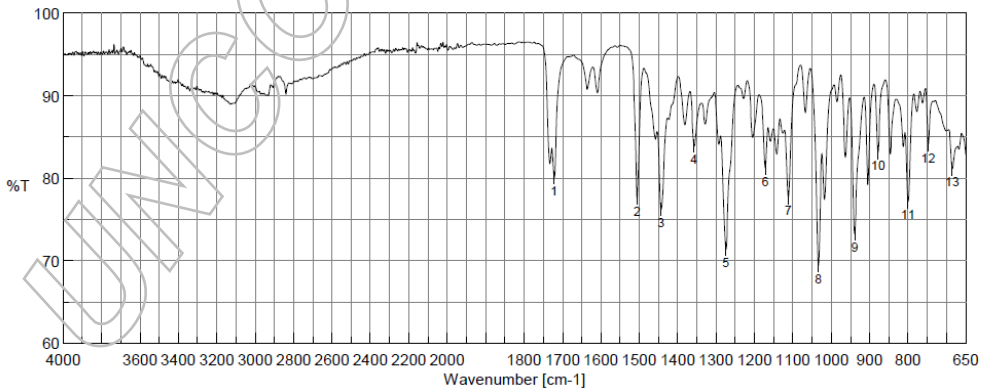
Method: 4.5 kV ESI+; vaporization temperature: 200 °C



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	1721.16	80.063
2	1505.17	77.5933
3	1442.49	76.176
4	1356.68	83.8943
5	1274.72	71.3749
6	1171.54	81.2165
7	1111.76	77.6724
8	1033.66	69.4163
9	939.163	73.264
10	878.417	83.1087
11	800.314	77.1529
12	747.281	84.0634
13	684.606	81.1186

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

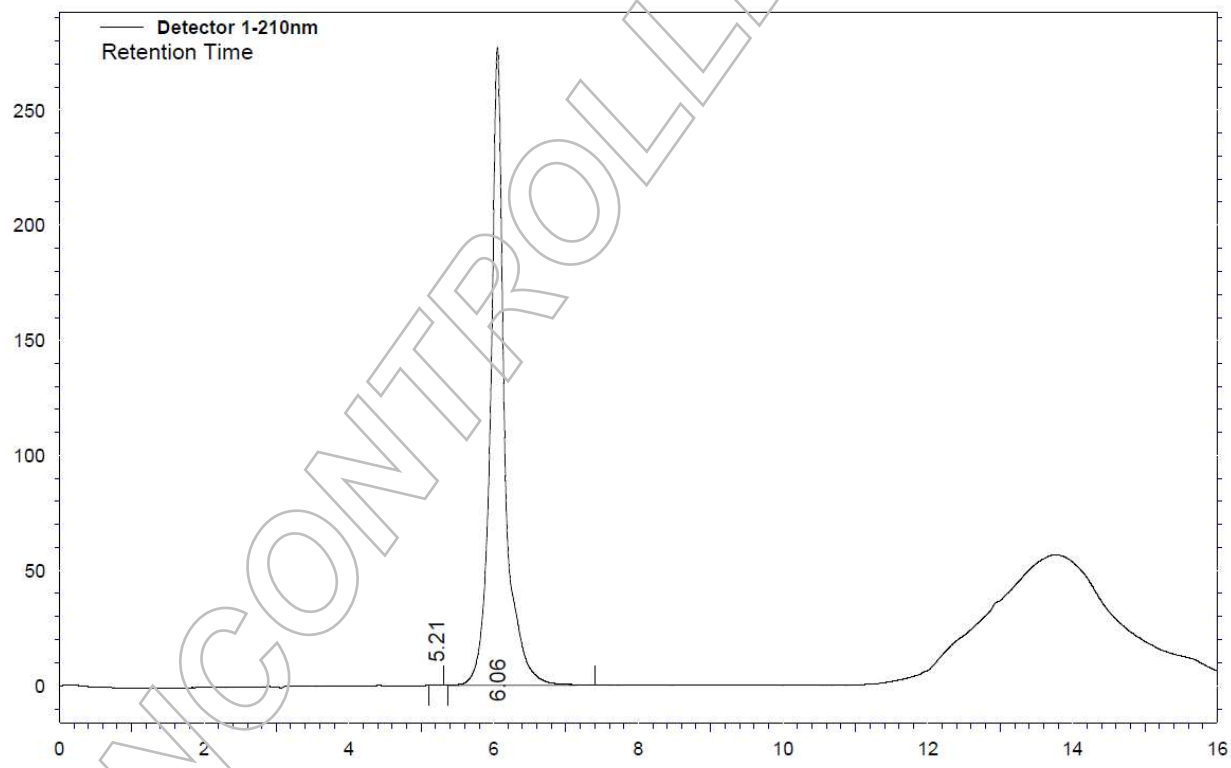
II. Purity

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:
Discovery HS F5 3 µm, 150 x 4.0 mm	0.5 ml/min, 40 °C 0–6 min Water/Acetonitrile 75/25 6–9 min Water/Acetonitrile to 20/80 9–11 min Water/Acetonitrile to 75/25 11-16 min Water/Acetonitrile 75/25 (v/v); 0.1 % H_3PO_4	DAD 210 nm	Auto 1 µl; 0.1148 mg/ml in Water/Acetonitrile 50/50 (v/v)



Area Percent Report - Sorted by Signal

Pk #	Retention Time	Area	Area %
1	5.21	1548	0.04
2	6.06	3742171	99.96
Totals		3743719	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	99.96 %
Number of results	n=3
Standard deviation	< 0.01 %

IIb. Water Content

Method: Karl Fischer titration

Results:

Average	5.54 %
Number of results	n=3
Standard deviation	0.04 %

IIc. Residual Solvents

Method: ^{1}H-NMR

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

III. Final Result

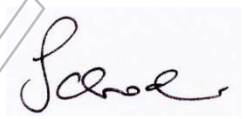
Chromatographic purity (HPLC)	99.96 %
Water content	5.54 %
Residual solvents	No significant amounts of residual solvents were detected (< 0.05 %).
Assay (100 % method)[1]	94.42 %

The assay is assessed to be 94.4 % ‘as is’

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

Release Date:

Luckenwalde, 2015-06-08



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.

LoGiCal® produced by LGC