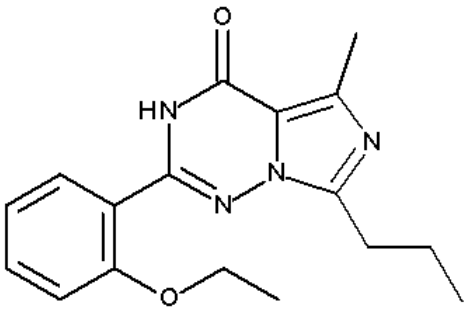
Certificate of Analysis

Reference Standard

Desulfovardenafil (2-(2-Ethoxyphenyl)-5-methyl-7-propyl-3H-imidazo[5,1-f][1,2,4]triazin-4-one)



Molecular Formula:	$C_{17}H_{20}N_4O_2$
Molecular Weight:	312.37
CAS Number:	224789-21-3

Catalogue Number:	LGCFOR1569.01
Lot Number:	67223
Long-term Storage:	2 to 8 °C, dark
Appearance:	white solid
Melting Point (DSC):	148 °C
Assay 'as is':	99.5 %

Date of shipment: **2020-November-30**

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

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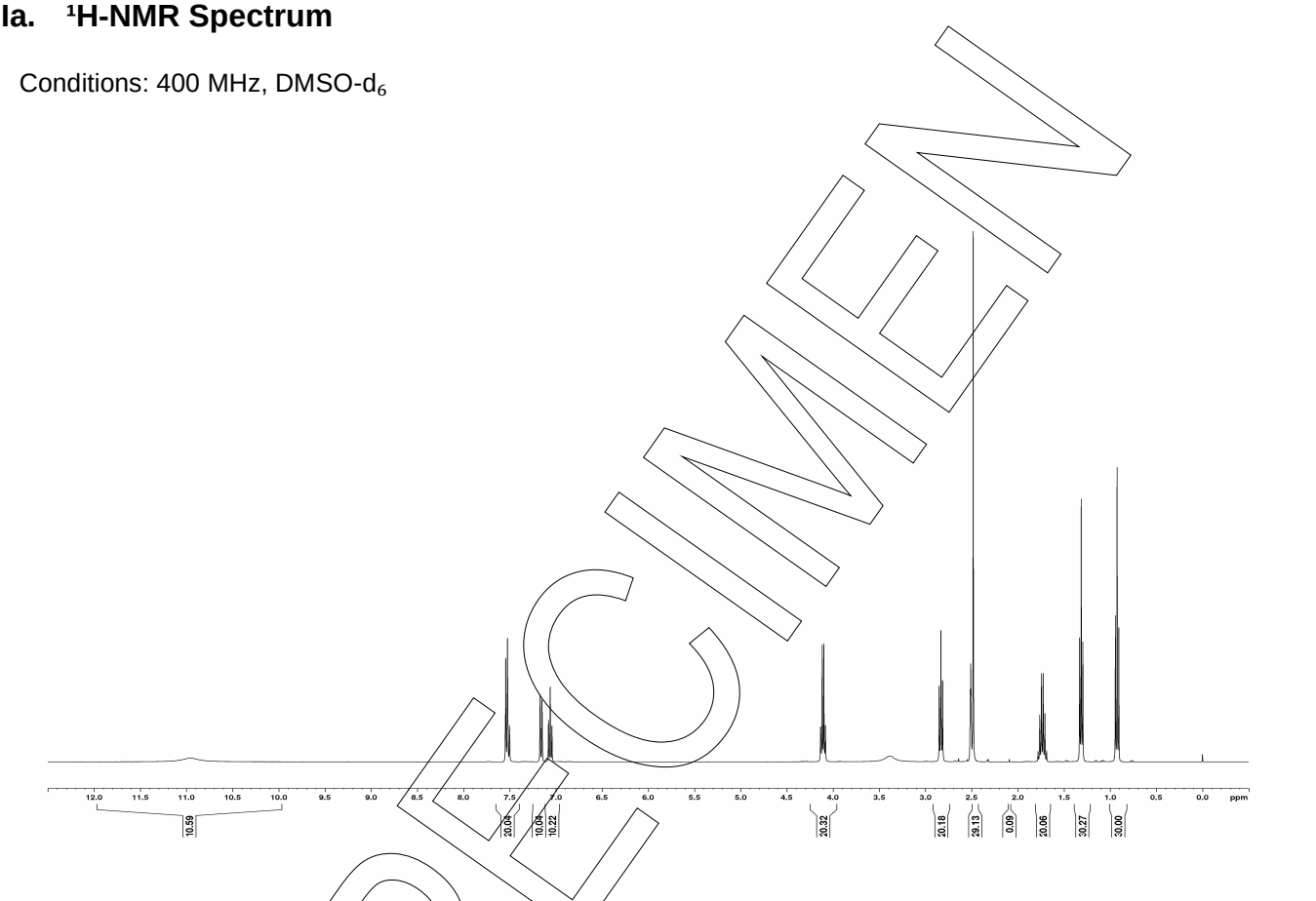
I. Identity

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

Ia. ^{1}H-NMR Spectrum

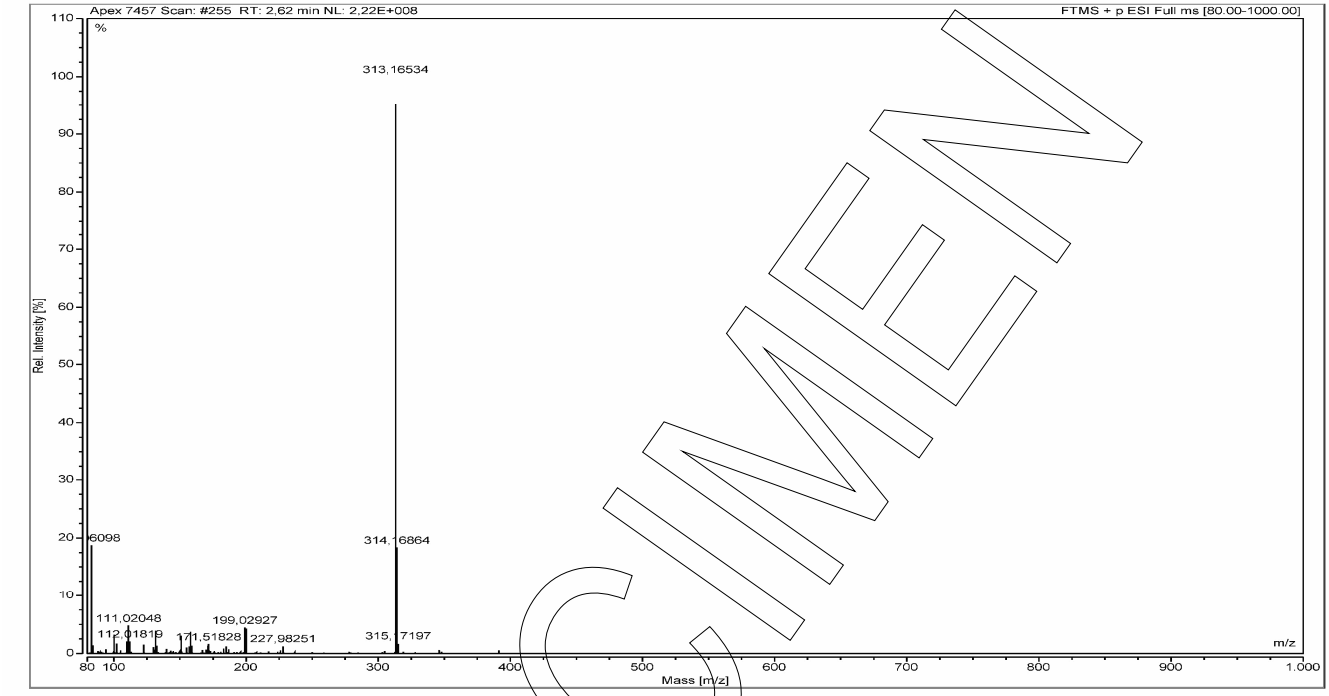
Conditions: 400 MHz, DMSO-d_6



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

Ib. Mass Spectrum

Method: HRMS; 3.5 kV ESI+; capillary temperature: 269 °C



Theoretical value: 313.16590

The signal of the MS spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

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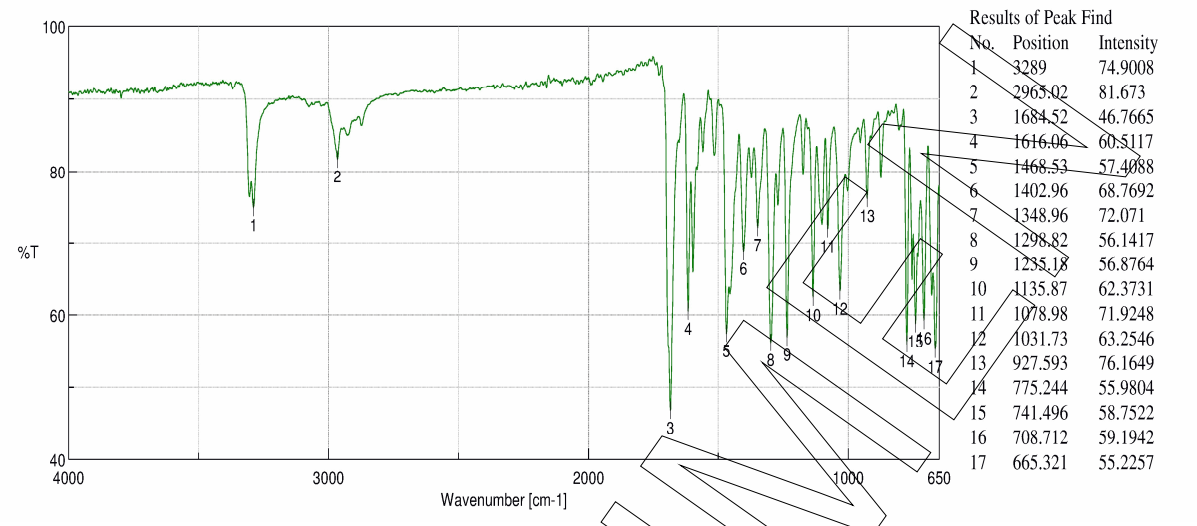
Ic. IR Spectrum

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



Results of Peak Find

No.	Position	Intensity
1	3289	74.9008
2	2965.02	81.673
3	1684.52	46.7665
4	1616.06	60.5117
5	1468.53	57.4088
6	1402.96	68.7692
7	1348.96	72.071
8	1298.82	56.1417
9	1235.18	56.8764
10	1135.87	62.3731
11	1078.98	71.9248
12	1031.73	63.2546
13	927.593	76.1649
14	775.244	55.9804
15	741.496	58.7522
16	708.712	59.1942
17	665.321	55.2257

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

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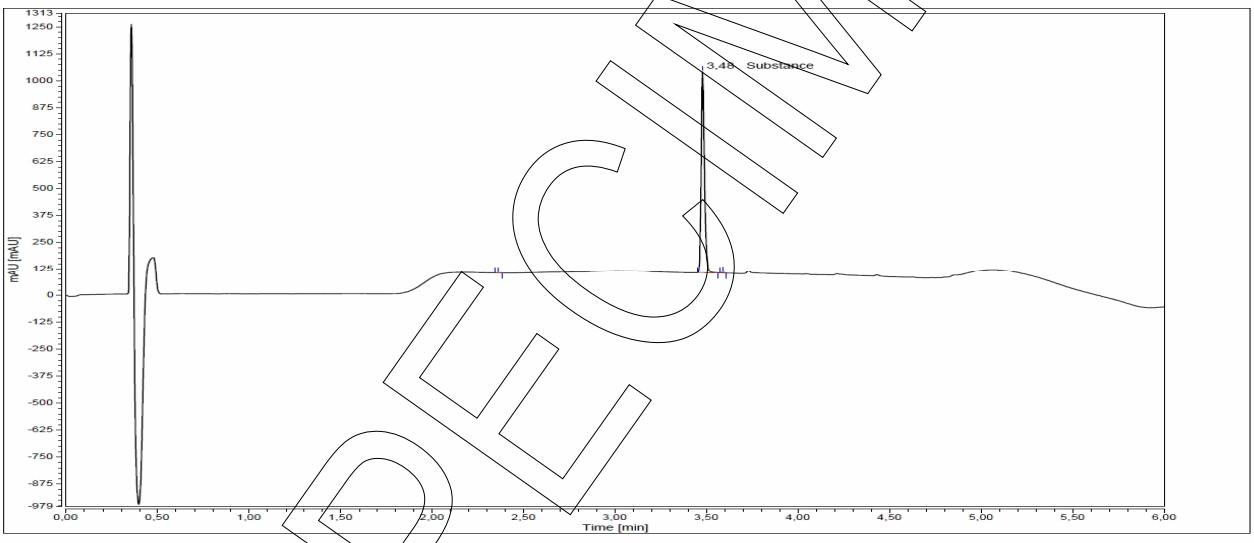
II. Purity

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:**
Cortecs UPLC C18 + 1.6 µm, 75 x 2.1 mm	0.50 ml/min, 40 °C mob. Phase A: Water, 0.1 % HCOOH mob. Phase B: Acetonitrile, 0.1 % HCOOH 0-1 min A/B 98/2 1-4 min A/B to 2/98 4-5 min A/B to 98/2 5-6 min A/B 98/2 (v/v)	DAD 210 nm	Auto 2 µl; 0.044 mg/ml in Methanol



Area Percent Report - Sorted by Signal

Pk#	Retention Time	Area	Area %
1	2.358	0.0232	0.12
2	3.476	19.4077	99.59
3	3.586	0.0558	0.29
Totals		**19.4867**	**100.00**

For the calculation the system peaks were ignored. The content of the analyte was determined as the ratio of the peak area of the analyte and the cumulative areas of the purities, added up to 100 %.

Results:

Average	99.59 %
Number of results	n=3
Standard deviation	0.02 %

IIb. Water Content

Method: Karl Fischer titration

Results:

Average	0.07 %
Number of results	n=3
Standard deviation	0.01 %

IIc. Residual Solvents

Method: ^{1}H-NMR

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

III. Final Result

Chromatographic purity (HPLC)	99.59 %
Water content	0.07 %
Residual solvents	No significant amounts of residual solvents were detected (< 0.05 %)
Assay (100 % method)[1]	99.52 %

The assay is assessed to be 99.5 % ‘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-February-27

Signed:

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

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