LoGiCal®
produced by LGC

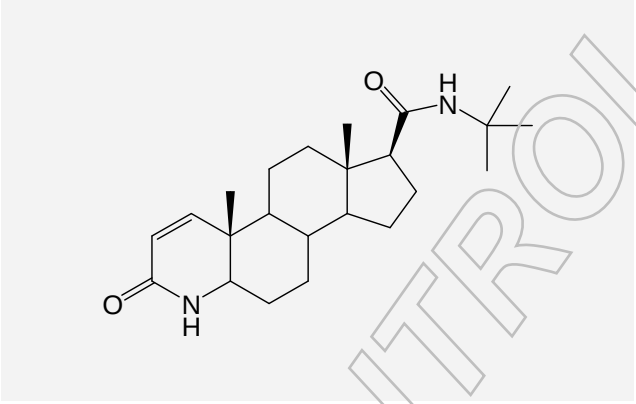
Certificate of Analysis

Reference Substance

Finasteride

Catalogue Number:	LGCFOR0415.00
Lot Number:	12364
Molecular Formula:	$C_{23}H_{36}N_2O_2$
Molecular Weight:	372.54
CAS Number:	[98319-26-7]

Long-term Storage:	2 to 8 °C, dark
Appearance:	white solid
Melting Point:	256 °C
Assay 'as is':	99.3 %



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.

Release Date: 2012-02-09

LGC GmbH

Dr. Sabine Schröder
Product Release

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LGC Quality | ISO 9001:2008 DQS 102448 QM08

LGC Standards
Excellence through measurement

LGC GmbH, Im Biotechnologiepark, TGZ II, D-14943 Luckenwalde, Germany

6 pages

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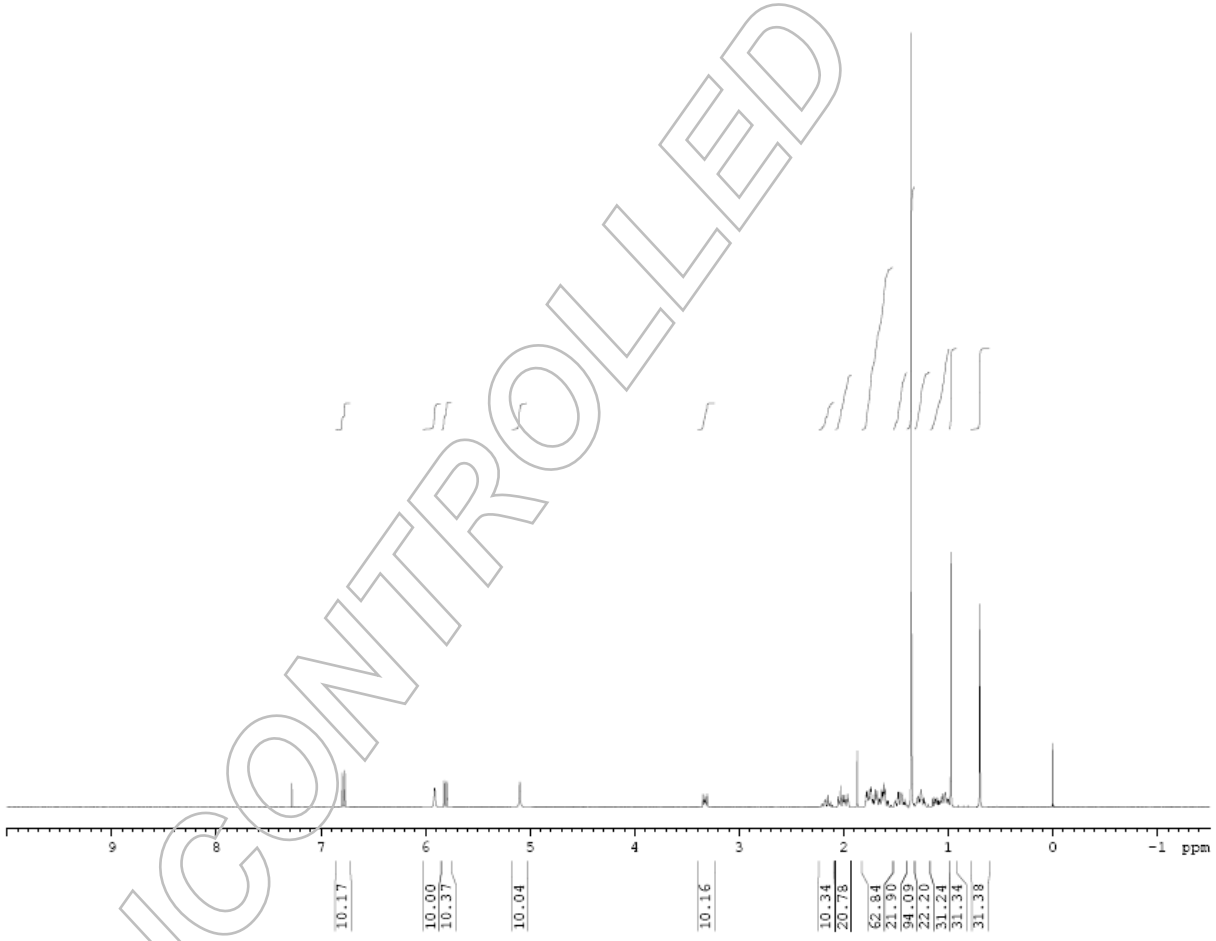
I. Identity

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

Ia. ^{1}H-NMR Spectrum

Conditions: 400 MHz, $CDCl_3$

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



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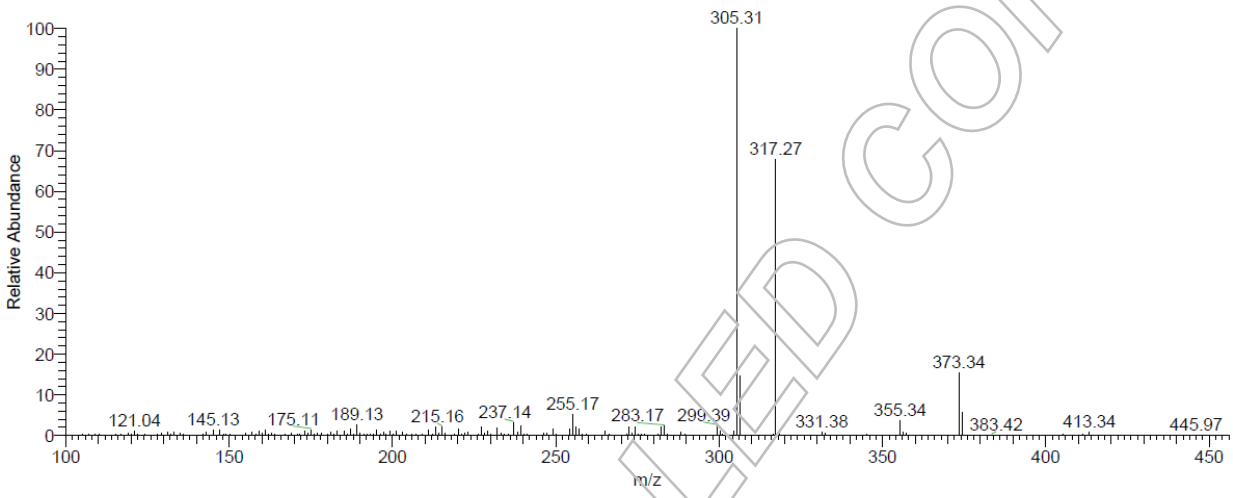
Ib. Mass Spectrum

Method: 4.5 kV ESI; vaporization temperature: 200 °C, direct inlet



m/z	fragments
373	[MH]

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

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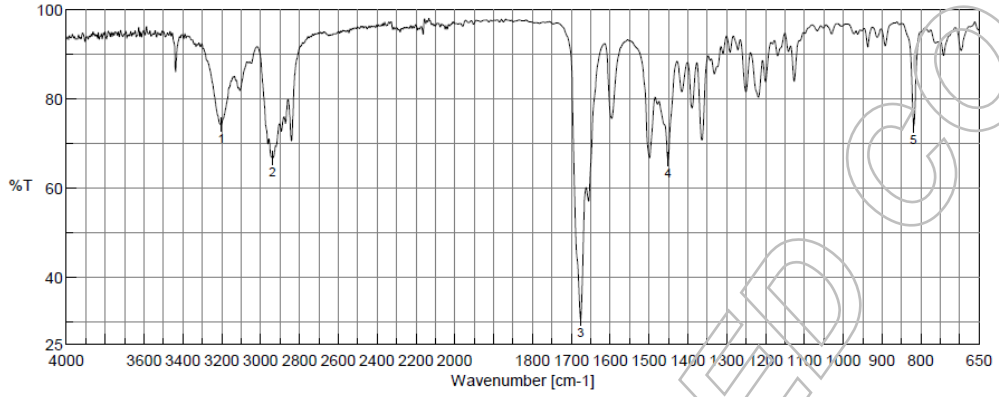
Ic. IR Spectrum

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



Result of Peak Picking

No.	Position	Intensity
1	3202.22	74.1877
2	2938.02	66.6563
3	1675.84	30.6011
4	1450.21	66.3388
5	818.634	73.8466

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:	**Conditions:**	**Detector:**	**Injector:**
Luna C 18(2) 5 µm, 250 x 4.6 mm	1.0 ml/min, 40 °C 0-13 min Water/Acetonitrile 55/45 13-20 min Water/Acetonitrile to 30/70 20-25 min Water/Acetonitrile to 55/45 25-35 min Water/Acetonitrile 55/45 (v/v); 0.1 % H_3PO_4	DAD 210 nm	Auto 7 µl; 0.061 mg/ml in Acetonitrile

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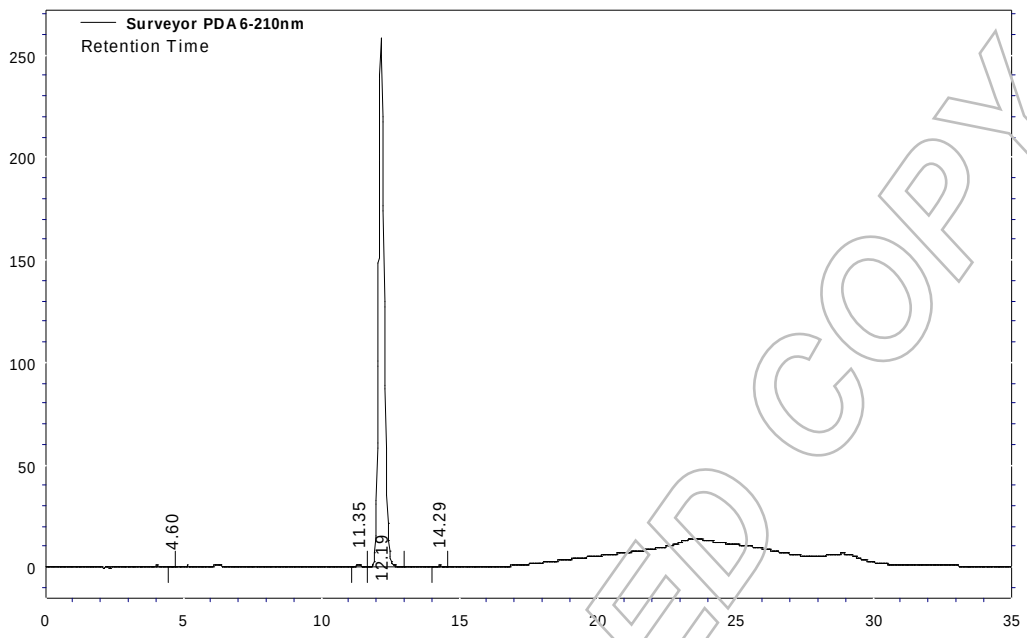

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Area Percent Report - Sorted by Signal

Pk #	Retention Time	Area	Area %
1	4.60	868	0.02
2	11.35	10523	0.28
3	12.19	3723086	99.55
4	14.29	5310	0.14
Totals		3739787	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	99.55 %
Number of results	n=6
Standard deviation	0.01 %

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III. Water Content

Method: Karl Fischer titration

Results:

Average	0.26 %
Number of results	n=2

IV. Residual Solvents

Method: ^{1}H-NMR

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

V. Final Result

Total impurities (HPLC)	0.45 %
Water content	0.26 %
Residual solvents	n. d. (not detected)
Assay (100 % method) [1]	99.29 %

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.

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

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

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

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