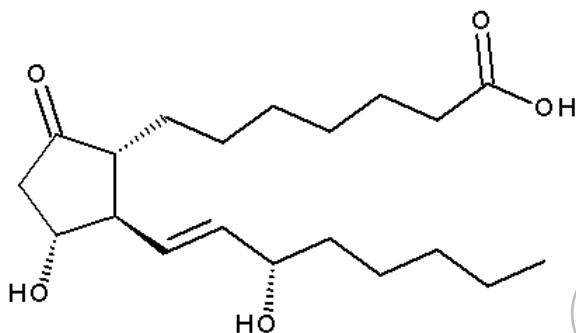




Certificate of Analysis

Reference Standard

Alprostadiol



Molecular Formula: $C_{20}H_{34}O_5$
Molecular Weight: 354.48
CAS Number: 745-65-3

Catalogue Number: LGCFOR1553.00
Lot Number: 77026
Long-term Storage: 2 to 8 °C, dark
Appearance: white solid
Melting Point (DSC): 117 °C
Assay 'as is': 100.2 %

Date of shipment: **2017-January-25**

This certificate is valid one year 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

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

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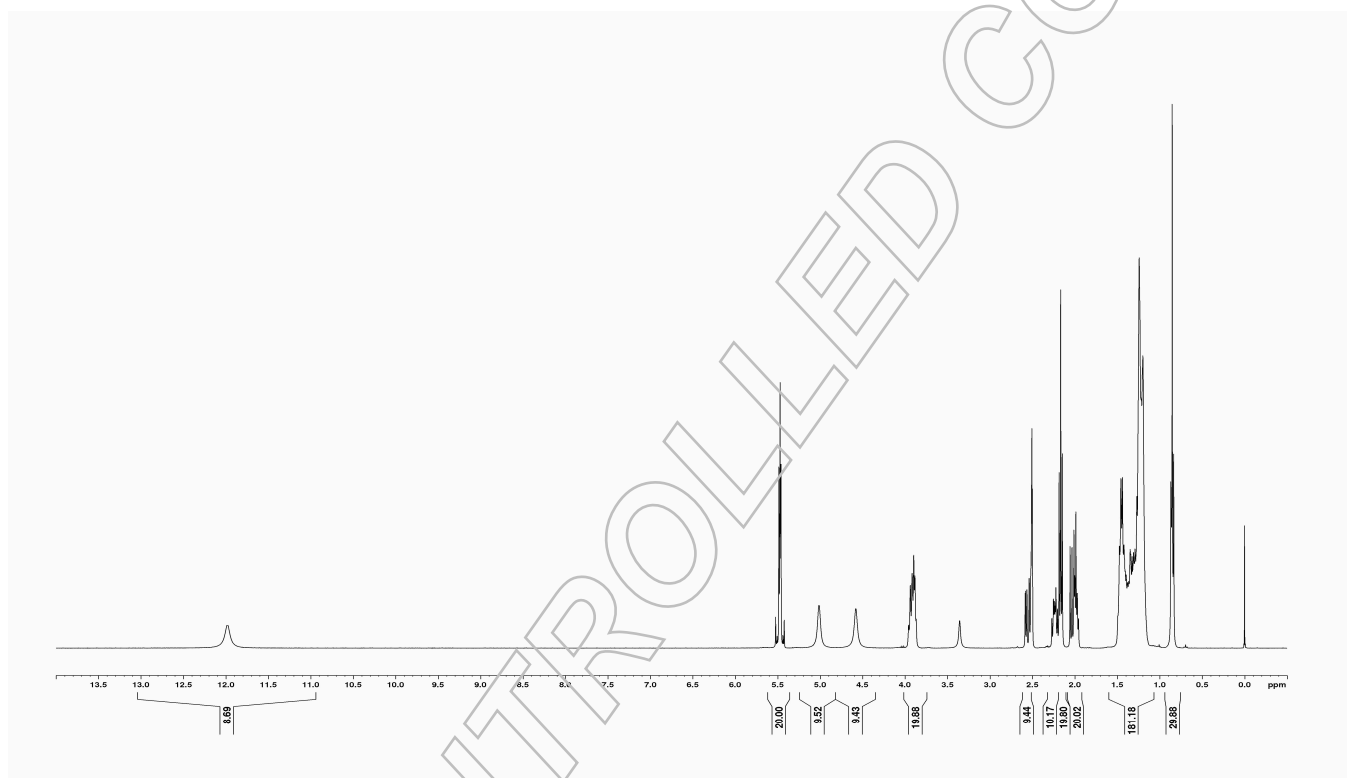


I. Identity

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

Ia. ^1H -NMR Spectrum

Conditions: 400 MHz, DMSO-d_6

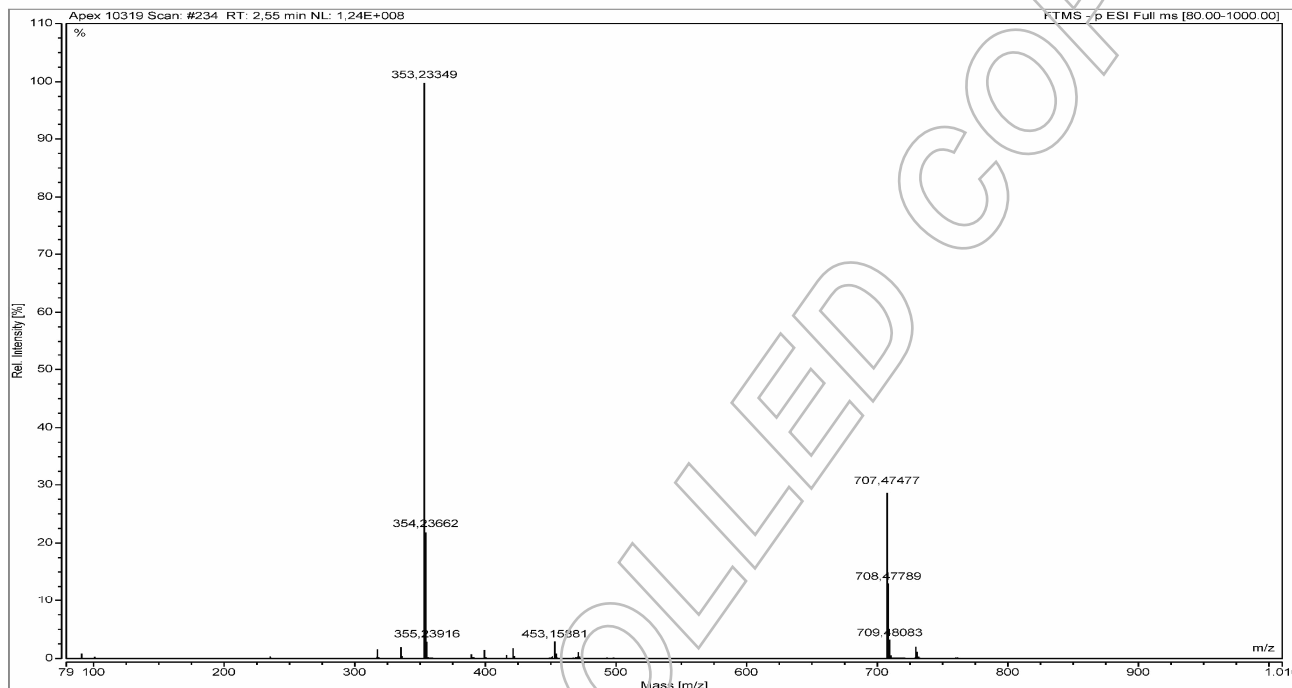


The structure is confirmed by the signals of the spectrum and their interpretation.



Ib. Mass Spectrum

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



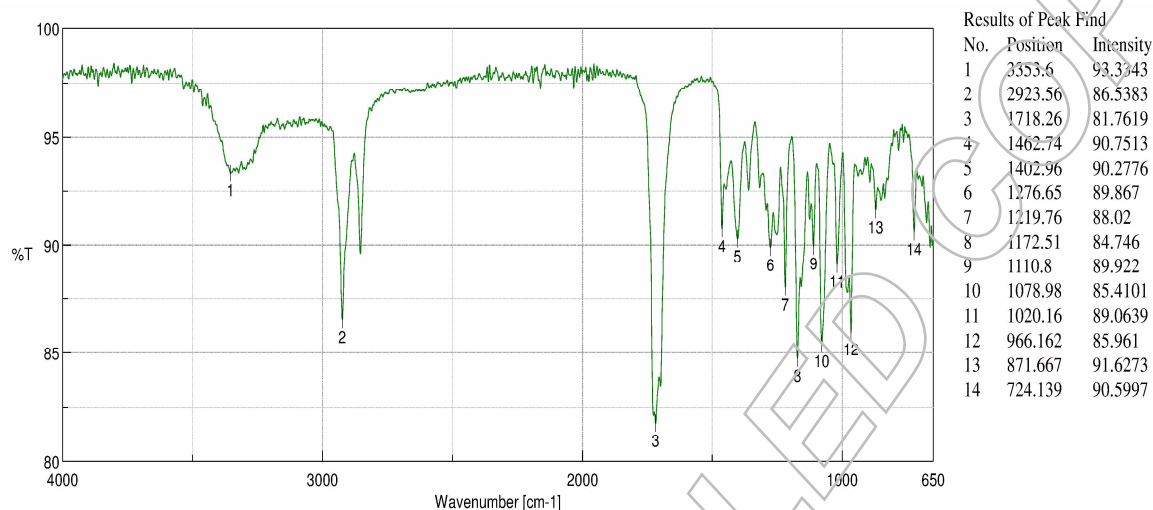
Theoretical value: 353.23335

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

II. Purity

IIa. Water Content

Method: Karl Fischer titration

Results:

Average 0.06 %

Number of results n=3

Standard deviation 0.01 %

IIb. Residual Solvents

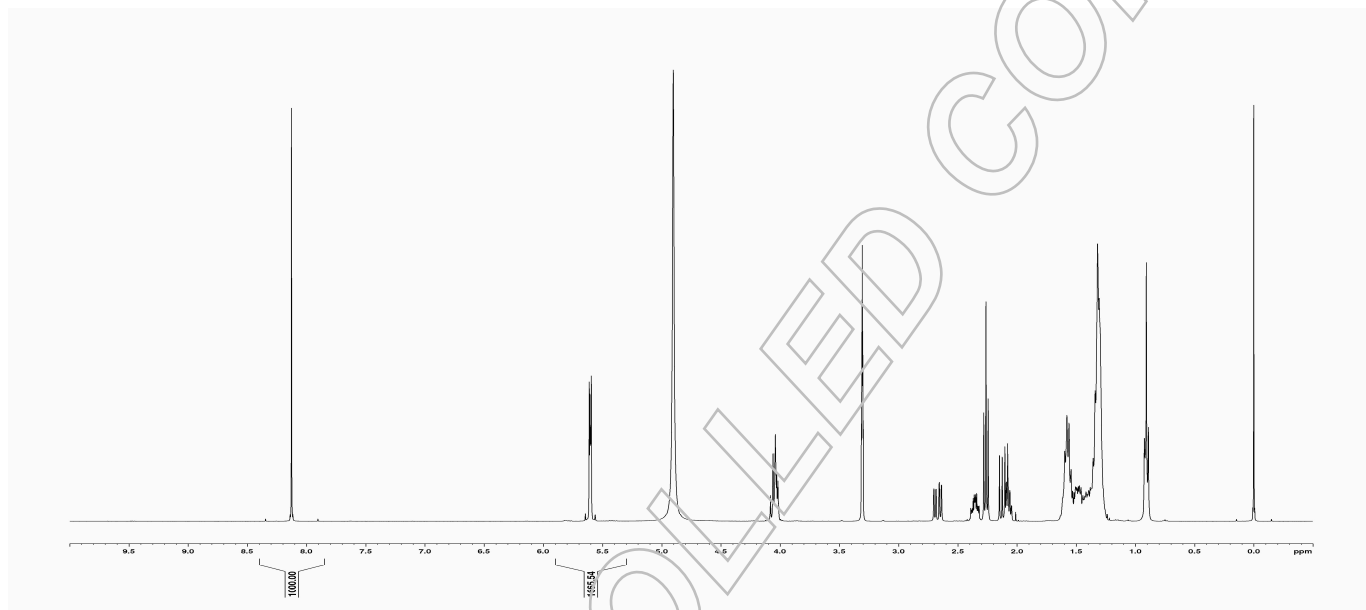
Method: $^1\text{H-NMR}$

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



III. Assay by quantitative NMR spectroscopy

The assay of the reference substance was established by quantitative NMR spectroscopy using CD_3OD as solvent and with 2,3,5,6-Tetrachloro-1-nitrobenzene (certified reference material, signal 7.9 - 8.4 ppm, 1 H) as internal standard.



Results:

Average	100.21 %
Number of results	n=6
Standard deviation	0.04 %



IV. Final Result

Water content	0.06 %
Residual solvents	No significant amounts of residual solvents were detected (< 0.05 %)
Assay	
Quantitative NMR spectroscopy	100.21 %

The assay is assessed to be 100.2 % '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-September-11

Signed:

Dr. Sabine Schröder
Product Release